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Work Assignment Form. (WebForms v1.0)

Performance Work Statement ICF Contract # EP-C-11-005 Work Assignment #5-04

Title: QMRA Activities to Support Criteria Development and Implementation

Work Assignment Contracting Officer Representative (WACOR):

John Ravenscroft (Mail Code 4304T)

Office of Water, Office of Science and Technology

Health and Ecological Criteria Division

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Health and Ecological Criteria Division

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Washington, DC 20460 Telephone #: 202-566-0740

E-mail: nappier.sharon@epa.gov

Period of Performance: January 1, 2016 through June 30, 2016

**Note: No CBI data will be needed in the course of this work assignment.

Contractor PWS: 3.1, 3.3, and 3.6

Background: EPA is issued new CWA 304(a) Recreational Ambient Water Quality Criteria (AWQC) in December 2012. The science underpinning the new criteria describes human health effects and water quality studies conducted in waters impacted primarily by human sources of fecal contamination. EPA would like to better understand the risks associated with other fecal sources and the potential wet weather impacts on surface waters. Quantitative Microbial Risk Assessment (QMRA) has been identified as a tool that the Agency can use to complement existing health data and to better understand the relative risks associated with non-human fecal sources of surface water contamination. The Agency's previously supported QMRA efforts have indicated that there are potentially significant differences in health risks associated with different sources of fecal contamination and additional efforts are needed to better inform the regulatory framework. This work assignment covers various aspects of further development and application of QMRA in support of Recreational AWQC development and implementation.

Quality Assurance: The tasks in this performance work assignment (PWS) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP (date: March 2012). Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the WACOR before activities covered by the additional QA language begin under this PWS.

Performance Work Statement (PWS): The scope of this work assignment will fall under the following task areas:

Task 1: Work plan, monthly progress reports and quality assurance

Task 1.1: Work plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.2: Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The WACOR will provide the checklist to the contractor. The contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in

developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Summary Report. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the checklist.

Task 2: General Project Support and Development of Technical Support Guidance

EPA is planning to make available Quantitative Microbial Risk Assessment (QMRA) guidance to States for consideration in developing site-specific Water Quality Standards (WQS) packages. Task 2 comprises the different facets of the QMRA guidance project and includes project planning, communication strategies, and guidance document development.

Task 2.1: Project planning and management

The contractor shall conduct project strategic planning in conjunction with the WACOR. The purpose of this subtask will be to develop a comprehensive plan that includes all related tasks and deliverables in the context of the Agency's Recreational Ambient Water Quality Criteria (RWQC) and implementation guidance. The planning shall include a discussion of each task will aid EPA in meeting its goals in relation to QMRA and the technical support guidance for implementation. Efforts under this task were conducted in the previous contract year. The contractor shall continue to maintain schedules listing all QMRA-related work with interim and final deliverable dates and quarterly project updates delineated.

Project milestones provided in this work assignment may be impacted by the results of this project planning. Any differences identified in these due dates will need to be identified and communicated via technical direction from the WACOR.

Task 2.2: Project communication support:

The contractor shall, based on technical direction given by the WACOR, provide support in preparing interim project updates and other materials for internal and external audiences. These may include but are not limited to short briefing documents and PowerPoint presentations. The contractor may also be directed to participate in and/or conduct briefings and meetings. The contractor may also be directed to prepare reports for communication outside the EPA based on deliverables generated by tasks under this work assignment. The contractor shall coordinate with the WACOR for the proper timing and need for these activities. A weekly update call with the WACOR will be required for this task, as needed.

A second major area under this task is QMRA outreach support. The contractor shall assist WACOR with internal and external outreach to EPA management, both at Headquarters and with Regional offices, States, and other Stakeholder groups.

EPA needs to communicate its efforts to a broad audience. From engaging other scientists on technical issues to discussing regulatory actions with stakeholders and the public, EPA needs to be keenly aware of effective communication strategies. For all tasks under this work

assignment, the contractor shall discuss with the WACOR ways to achieve effective communication objectives. The audience for specific deliverables may be different even though the analytical approach may be similar. Questions to cover with the WACOR should address the audience and purpose of the deliverable, ideas for finding effective presentation strategies, suggestions for achieving the communication objectives given differing formats (e.g., written versus oral).

The contractor may be requested to attend meetings of a scientific nature to present the results of the QMRA analyses to technical and non-technical audiences. All appropriate clearances and approvals required by Agency policy in support of any and all meetings shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under meeting-related activities and expenses shall not occur until this approval is obtained and provided by the EPA PO. At the time of the preparation of this work assignment, the following meetings of interest were known to the WACOR:

- 1) 2016 Recreational Waters Conference, April 12-15, New Orleans, LA
- 2) Water Microbiology Conference, May 17-19, UNC-Chapel Hill, NC

The contractor shall discuss with the WACOR the potential scope of presentations based on the work conducted under this work assignment, included during preceding contract years, and how those presentations align with the goals of the conferences.

Task 2.3: Development of QMRA Technical Support Guidance, QMRA framework:

The purpose of this task is to continue development and to produce communication materials for the use of QMRA in the development of site-specific recreational water criteria intended as the basis for water quality standards (WQS). Past efforts by the Contractor have concentrated mainly on non-human sources, but the framework itself should be robust enough to consider other differences or site-specific characteristics.

The contractor shall continue development of the Quantitative Microbial Risk Assessment (QMRA) framework for the purposes outlined above. This task shall build upon previous efforts conducted under B-04, Task 2.2 (QMRA guidance: how to conduct a QMRA for ambient waters, data needs and analytical approaches), and 1-04, 2-04 and 3-04, Task 2.3. The goal for this task will be to develop and to communicate the process by which QMRA can be used to derive alternative site-specific ambient water quality criteria for recreational use waters that will, in turn, be used to assemble a water quality standards (WQS) package. This deliverable can be considered part of the overall technical support guidance as detailed in other tasks below, and shall include a description and discussion of the process and framework whereby QMRA could be used as a basis for a site-specific WQS package.

The deliverable shall address the way(s) a State can determine if any given site is a good candidate for the development of a site-specific water quality standards package based on a QMRA-derived criteria value. The Contractor shall include a discussion of the components of water quality standards package and how QMRA can assist in developing a site-specific water

quality criteria value. To complete this part of the deliverable, the contractor shall meet with the WACOR, WQS coordinators or other personnel in SHPD and the Regions. Logistics of these meetings may require the contractor to attend meetings at EPA HQ. The contractor shall address the differing approaches a State could use in running a QMRA (i.e., differing level of effort related to complexity of analysis).

The contractor shall also consider the implications that the WQS package will be evaluated by EPA regional and headquarters personnel who will not necessarily have a technical background in microbiology, public health or risk assessment methodologies. Therefore, it will be *critical* that the contractor consider the end-user audience as the deliverable is being developed. Technical material shall be transparently and sufficiently conveyed. The narrative shall be thoroughly developed and any graphical materials shall be explained completely. No assumption should be made that the audience will internalize figures or tables. These considerations are quite important as this material will be used to inform the policy decisions needed for QMRA to be used effectively. Much consideration should be given to the current paradigm in this area; end-users that are not familiar with risk assessment in general and hampered by misunderstandings related to the past and current technical bases for the nationally recommended recreational water quality criteria. It will be crucial that the contractor develop effective communication and outreach materials if QMRA is to be applied effectively.

The primary deliverable was peer reviewed and submitted for management review in 2015. The contractor shall assist in responding to EPA comments and preparing a final version suitable for publication.

Task 2.4: Development of QMRA Technical Support Guidance, Volume A:

The purpose of this task is to develop a guide for use by States and localities for the purposes of deriving via the QMRA framework discussed in Task 2.3, site-specific criteria, notably for waters predominated by non-human sources of fecal contamination, for inclusion into WQS. This volume was reviewed by management in October 2014, revised and sent to peer review. The contractor shall assist the WACOR with responding to peer review comments and the second round of management comments prior to finalizing the document for publication on EPA's website. EPA's response to the peer review comments will need to be tracked in a spreadsheet (provided to the contractor by the WACOR). All comments will require a response. The contractor shall assist the WACOR in developing the communications strategy for the release of the document on EPA's website.

This guide should also provide information to EPA Regions who are tasked to evaluate State WQS packages. Volume A of this guidance shall concentrate on how to determine if a water body is eligible for the development of site-specific criteria, what information can be used to provide a line of evidence approach for determining sources of fecal contamination (i.e., how to build a sanitary characterization), differing approaches to conducting a Quantitative Microbial Risk Assessment (QMRA) (i.e., incorporate information from Task 2.3), the information needs for conducting a QMRA (at each level of effort), how to conduct a QMRA (i.e., how to build a transparent, clear, concise and reasonable risk assessment in support of public policy), deriving

a site-specific water quality criterion, preparing a site-specific water quality standards package, and other topics as needed to be specified by the WACOR (and in consultation with HECD's partners in SHPD). The main goal for this deliverable is produce guidance for States to use in developing microbial Water Quality Standards (WQS) that are scientifically defensible, protective of the recreational designated use, and meet EPA standards for consideration and potential approval.

This task will require the contractor to attend meetings with the WACOR and other staff at EPA Headquarters during the period of performance for the purposes of project updates, planning and communication.

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA PO.

The primary deliverable was peer reviewed and submitted for management review in 2015. The contractor shall assist in responding to EPA comments and preparing a final version suitable for publication.

Task 2.5: Development of QMRA Technical Support Guidance (TSG), Volume B:

The deliverable under this task shall provide the end user a sufficiently detailed background on QMRA and the use of microbial risk assessment in developing site specific water quality standards. This volume shall provide the technical bases for the material in Volume A (Task 2.4). While this volume is purposefully technical in nature, it should still be produced in a manner that would be accessible to the end user. This volume is currently under management review. This volume is scheduled to be published with Volume A.

The contractor shall include the following topics in the scope of technical materials: assessing human health risks from fecal contamination in surface waters; use and application of epidemiology in development of water quality standards around the world; use of risk assessment to help interpret and extend observational studies; factors affecting occurrence, prevalence, fate and transport of pathogens and fecal indicator bacteria in surface waters; potential effects of management practices on sources of fecal contamination and implications to potential human health risks; and, other topics as specified by the WACOR.

The primary deliverable was peer reviewed and submitted for management review in 2015. The contractor shall assist in responding to EPA comments and preparing a final version suitable for publication.

Task 2.6: Development of QMRA Technical Support Guidance (TSG), Volume C:

The purpose of this task is to document a series of QMRAs conducted on recreational use waters. Each QMRA would be made available or peer reviewed/published separately. This volume will discuss each and give more information to explain how each risk assessment fits into context with the materials in volumes A and B. The document provides context to compare and contrast discussion with EPA recommended ambient water quality criteria for recreational waters and other risk assessments. The Quantitative Microbial Risk Assessments (QMRAs) are discussed as examples of how QMRA was used to address specific risk management questions. This compilation volume will be published with Volumes A and B and should be considered to be on the same schedule for completion.

The contractor may be required to attend meetings with SCCWRP to discuss planning, scoping, conduct, or analyses associated with the case study project. As mentioned before, all appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA PO.

The primary deliverable was peer reviewed and submitted for management review in 2015. The contractor shall assist in responding to EPA comments and preparing a final version suitable for publication.

Task 2.7: Support for Southern California Coastal Water Research Project (SCCWRP) case study

The LA Regional Water Control Board, SCCWRP and EPA are collaborating on a project to characterize human health risks via QMRA from recreational water exposure at a predominantly non-human fecal-impacted beach in southern California. The potential beach locations are in Southern California. The second main goal of this effort is to use the QMRA results to inform the development of a site-specific water quality standard for submission and evaluation by EPA Region 9. The third goal of this effort is to document the experience as a "case study" for potential application at other candidate sites.

The Health and Ecological Criteria Division's participation in this project will be to aid in the planning and scoping of the project, provide QMRA support, and engage the regional water control board, EPA Region 9, and the local Non-government organizations (NGOs) in the development and evaluation of a site-specific water quality standard package. The contractor shall assist the WACOR with the QMRA-related aspects of this project. The contractor shall participate in discussions with the WACOR along with SCCWRP and the workgroup to help with project planning, scoping, QMRA analysis, interpretation of the results, and development of communication strategies for the purpose of deriving site-specific recreational water criteria for a beach predominantly impacted by non-human fecal contamination.

This task is considered ongoing with continued engagement with SCCWRP and other interested parties in California, such as the CA state and/or regional waterboards. California has multiple efforts evaluating the use of source tracking and risk assessment techniques in water quality management and public health protection. EPA may be requested to aid in the interpretation of the technical results and policy implications.

Task 2.9: Updating the Microbial Risk Assessment Tools Document -- This task is complete.

Task 3: QMRA anchoring

Task 3.1: Marine National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) studies

Previous efforts under this task are complete. No additional analyses are envisioned at this time.

Task 3.2: Marion et al. study

This task is ongoing. The contractor shall assist in preparing a report suitable for internal management review submitted to WACOR within two weeks of receiving OSU input. Comments from this review shall be discussed with the WACOR and the report revised accordingly. A final report suitable for peer review shall be submitted to WACOR within 1 week of receiving comments.

Task 3.3: Boquerón

The contractor shall assist the WACOR with QMRA-related analysis of the water quality and health data collected as part of the Boquerón health studies in 2009. Previous analyses have concentrated on beach exposures and interpretation of the epidemiological results. A second round of analyses are planned for this option year include evaluating discharge and effluent data for potential human health risks. The contractor prepared a problem formulation discussing the scope of the QMRA during the previous contract year. The next step for this project will involve planning the analysis plan and conducting the QMRA. The contractor shall discuss and complete the analysis plan with the WACOR by the end of January 2016. Based on the scope and complexity of the analysis plan, the contractor shall also discuss project planning with the WACOR to produce a project schedule including the completion of the QMRA by the end of May 2016.

Task 3.4: QMRA anchoring communication support

The contractor shall develop communication materials for the task 3 QMRAs aimed at non-technical and/or policy-oriented audiences. Materials aimed at the general population may also be needed and shall be prepared by the contractor when technical direction is received. The contractor shall discuss the importance of the findings of the Task 3 efforts, how they fit into context with other QMRA and other results, and any science or policy implications. Other topics to be included in these materials will be discussed as needed with the contractor.

Task 4: Relative QMRA refinement

Task 4.1: Evaluating source and receptor locations

This task shall continue support for efforts begun under B-04. The contractor shall meet with the WACOR to develop a list of modeling needs (e.g., FRAMES-related) to support implementation of QMRA. The contractor shall also coordinate with the WACOR to discuss with other EPA personnel about advancements in dose response modeling (e.g., animal studies translated to human health estimates).

The contractor shall continue to discuss with the WACOR and ORD-Athens personnel the current capabilities for fate and transport modeling in the context using the QMRA framework for deriving water quality standards. The WACOR will need to have these discussions documented for use with communication with management. This task is considered to require a low level of effort during the period of performance.

Task 4.2: Relative QMRA refinement: QMRA analysis of mixed fecal sources

Similar to Task 4.1, the contractor shall support efforts to further refine the risk analysis for mixed fecal sources by incorporating the fate and transport and meteorological parameter into the modeling. This is an ongoing collaboration between HECD and ORD-Athens.

Task 5: Primary and Secondary Contact evaluations

The purpose of this task is to evaluate health risks associated with different water-based activities performed in the US. This task will be part of the scientific basis for policy measures to place activities into appropriately protective recreational use categories (e.g. primary contact recreation, secondary contact recreation), and to determine the level of water quality necessary to protect individuals engaging in each of these activities.

The contractor submitted a draft Quantitative Microbial Risk Assessment (QMRA) report during the base year under this task. For this work assignment, the contractor may be asked to provide responses to questions from WACOR on the analysis and conclusions contained in the deliverable. The contractor may also be requested to update this document. The contractor shall consider this task a low level of effort task during the option year.

Task 6: Children's Health, Sensitive Subpopulations, Alternate Study designs, and Environmental Justice evaluations

Task 6.2: Alternate epidemiology study designs

EPA is interested in comparing results from epidemiology studies conducted with alternative study designs. The Agency has conducted past efforts in this area to identify appropriate data sets and design an analytical approach for that data. The contractor shall build upon those past efforts and secure data from an RCT (randomized control trial) epidemiology study sufficient for

a comparative analysis with a PC (prospective cohort) design. The contractor shall conduct the following activities:

Coordinate with the investigators on an RCT study to obtain the raw data from that study and re-analyze the results using the statistical methods employed by Wade and colleagues for the EPA epidemiology studies. This analysis will provide an indication of whether or not results from RCTs and PCs can be compared directly and will help to answer the question of whether the differences observed in existing epidemiology studies are due to the study design or other factors.

Use a QMRA framework to translate results from an RCT to one that is comparable to a PC study. Conduct sensitivity analyses to identify the model parameters that most strongly influence the results. Compare the results with those from the first analysis. The contractor shall report findings to WACOR in a memorandum, including potential next steps for this analysis.

Efforts conducted in the base year resulted in the identification of potential datasets for this analysis. However, there has been reluctance from external researchers to share the data needed for this comparison. This subtask is included here to maintain the potential for this analysis in this option year, but the contractor should consider this subtask as a placeholder and low priority. Should data become available, the contractor shall discuss the path forward with the WACOR before any LOE is expended on this task.

Task 7: Chicago Area Waterways (CAWS) QMRA -- This task is complete.

General Requirements of the Work Assignment and Schedule:

<u>Due Dates</u>: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

<u>Delays</u>: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

<u>Draft Documents</u>: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. WACOR will provide comments on draft submissions prior to submission of final documents.

<u>Final Documents</u>: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Milestone/Deliverable Table

Task #	Milestones and Due Dates
1.1	Within 15 calendar days of receipt of work assignment
1.2	Discuss with WACOR within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
2.1	Initial planning meeting to be held within 15 calendar days of receipt of work assignment. Meeting shall update project Gantt chart, goals and objectives statement, and gap analysis due within 2 weeks of initial meeting. Drafts of this deliverable would be expected at the close of the initial meeting. Subsequent meetings to be held regularly thereafter.
2.2	After the workplan approval, throughout the period of performance. Other communication materials will be dependent on the analytical results.
2.3	Include as part of Volume A
2.4	Respond to mgmt. comments – in conjunction with WACOR – 1 week after receiving mgmt. comments and approval. Estimated EPA publication date is March 2016.
2.5	Same schedule as Vol A.
	1.1 1.2 2.1 2.2

QMRA TSG: Vol C	2.6	Vol C mainly consists of reports prepared individually under other tasks - refer to those tasks for component schedules. Respond to reviewer comments as needed. For supplemental text expanding on those reports; same schedule as Vol A.
Support for SCCWRP study	2.7	Provide QMRA related planning, scoping, analysis, interpretation, and site-specific standard derivation support. Attend workgroup meetings at SCCWRP approximately once per year. Ongoing low level of effort throughout the period of performance.
Task 3: QMRA Anchoring		
Marine NEEAR reverse QIMRA	3.1	Task is complete.
Marion anchoring QMRA	3.2	Update report based on EPA and OSU comments and other analyses, with 1 week of receiving OSU input. Updated draft will be reviewed by HECD management. Mgmt comments will be addressed and final report to be submitted for peer review by end of January 2016.
Boqueron QMRA	3.3	Additional QMRA analyses using data collected as part of Boqueron health studies. Draft problem formulation submitted in 2015. The contractor shall begin to develop analytical approach based on technical direction from the WACOR.
QMRA Communications Support Task 4: Relative QMRA refinement	3.4	Non-technical, policy oriented communication materials, within 1 month of workplan approval. Materials for general audiences due date to be determined by technical direction. Meeting and presentation at EPA HQ to be determined.
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Evaluating sources and receptor locations	4.1	Ongoing throughout the period of performance. Periodic teleconference calls (e.g., bimonthly) with WACOR, ICF, and ORD-Athens. Deliverables for this task include notes of teleconference meetings and synopses of modeling developments and capabilities used for internal communication.
Refinement of QMRA analyses of mixed fecal sources	4.2	Low LOE effort throughout the period of performance.
Task 5: Primary and Secondary Contact		
Communications support		Low LOE effort; as needed throughout the period of performance.
Task 6: Sensitive Subpopulations and alternate study designs		
Alternative epidemiology study design	6.2	Low LOE effort; continue efforts to identify RCT data sets.
Task 7: CAWS QMRA support		
Update draft QMRA addressing EPA comments and inclusion of additional questions/information.	7.1	Task is complete.

MEETINGS, CONFERENCES, TRAINING EVENTS, AWARD CEREMONIES AND RECEPTIONS:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA Contract Level Contracting Officer Representative (COR) as needed and provided to the contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA COR.

TECHNICAL DIRECTION:

The COR or an authorized individual is permitted to provide technical direction. Technical direction must be within the statement of work of the contract and includes: (1) Direction to the contractor which assists the contractor in accomplishing the Statement of Work, (2) Comments on and approval of reports or other deliverables. Technical direction will be issued in writing or confirmed in writing within five (5) calendar days after verbal issuance. One copy of the technical direction memorandum will be forwarded to the Contracting Officer and the Contracting Officer Representative.

CONTRACTOR IDENTIFICATION:

Contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, Contractor personnel shall wear a badge which identifies the individual as a contractor employee. Contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

SPECIAL CONDITIONS:

- A. The contractor shall provide all materials written under these tasks to the EPA WACOR, as per work assignment, in electronic form and 5 hard copies of the final products. Electronic versions shall be in Microsoft Word and/or PDF.
- B. The contractor shall provide signed copies of all consultant agreements for the experts required in support of this work assignment to the EPA Contracting Officer.

CONFIDENTIALITY:

Some of the work assigned under these tasks will be to draft, edit and review sensitive program and organizational information. The contractor shall not discuss the contents of the conference or meeting discussions with anyone that did not participate in those discussions.

NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT:

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the EPA COR or the EPA Contracting Officer.

Peer Review Handbook	Page 5
Manager's Planning Checklist for Peer Review	
1) Title of Work Product: QMRA for estimating human from sources of fical containing tron 2) What Decision/Rute/Regulation/Action Does this Work Product Support development and implementation of Recrea	Leath ris
3) Designation of Scientific and Technical Work Products G Is the work product scientific or technical yesno? G Is the work productinfluential scientific information (ISI),highly influential sessessment (HISA), orother? (See Section 2.2.3 and 2.2.4 of the Peer Rev for an explanation of these terms).	ntial scientific
 4) Determining What Peer Review is Needed G If ISI or HISA, peer review is needed. G If not influential, is peer review still needed? G What peer review mechanism is needed (internal and/or external)? G When does the review need to be done? G How much time will be needed to conduct/complete the review? G Are there court ordered deadlines or other constraints? G Has senior management (ΛΑ/RΑ/others) been informed of progress/problems G What would constitute success for this review? 	?
 5) Determining the Resources for Peer Review G What is the priority of this project relative to other projects in the same office? G What resources are needed to conduct the review? G What are the impacts of the review on personnel? G Who will lead the peer review? G Who will conduct the peer review? G Who will maintain the peer review record? G Where will the peer review record be kept? G What mechanism will be used for the peer review? G Has the charge been developed? G Has internal and external coordination been initiated/completed? G Have arrangements for interim/final sign-offs (e.g., for the charge, the panel, or to the final work product) been made? G How will results of the review be presented and addressed in the final work programble, in an accompanying appendix — as well as changes in the work product been entered into the Science Inventory? 	on any changes oduct (e.g., in a
6) Comments:	

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Performance Work Statement ICF Contract # EP-C-11-005 Work Assignment #5-04 Amendment 1

Title: QMRA Activities to Support Criteria Development and Implementation

Work Assignment Contracting: John Ravenscroft (Mail Code 4304T)

Officer Representative (WACOR) Office of Water, Office of Science and Technology

Health and Ecological Criteria Division

1200 Pennsylvania Ave, N.W.

Washington, DC 20460 Phone (202) 566-1101

E-mail: ravenscroft.john@epa.gov

Alternate WACOR: Sharon Nappier (Mail Code 4304T)

Office of Water, Office of Science and Technology

Health and Ecological Criteria Division

1200 Pennsylvania Ave, N.W.

Washington, DC 20460 Telephone #: 202-566-0740

E-mail: nappier.sharon@epa.gov

Contractor PWS: 3.1, 3.3, and 3.6

Period of Performance: WA Amendment Issuance through June 30, 2016

**Note: No CBI data will be needed in the course of this work assignment.

Purpose of Amendment: The purpose of this amendment is to descope specific activities associated with Tasks 2.3, 2.4, 2.5 and 2.6. These tasks referred to assistance with responding to EPA comments and preparing a final version suitable for publication. The final management review will not occur in time for the Contractor perform those prior to the end of the period of performance. Therefore, the specific activities associated with these tasks mentioned in the original work assignment need to be descoped. Unless specifically mentioned here, the other language contained in the original work assignment still applies (e.g., Information Quality Guidelines, QA section, etc.). The approved workplan provides cost and LOE estimates at the highest task level (e.g., Task 1, Task 2, etc.) and does not break out the individual sub-tasks mentioned above. The Contractor shall submit a revised cost estimate to reflect the reduction in scope within 5 days after receipt of this amendment.

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Performance Work Statement ICF Contract # EP-C-11-005 Work Assignment #5-04 Amendment 2

Title: QMRA Activities to Support Criteria Development and Implementation

Work Assignment Contracting Officer Representative (WACOR):

John Ravenscroft (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101

E-mail: ravenscroft.john@epa.gov

Alternate WACOR: Sharon Nappier (Mail Code 4304T)

Office of Water, Office of Science and Technology

Health and Ecological Criteria Division

1200 Pennsylvania Ave, N.W.

Washington, DC 20460
Telephone #: 202-566-0740
E-mail: nappier.sharon@epa.gov

Contractor PWS: 3.1, 3.3, and 3.6

Period of Performance: WA Amendment Issuance through August 31, 2016

**Note: No CBI data will be needed in the course of this work assignment.

Purpose of Amendment: The purpose of this amendment is to provide additional LOE to support activities under this work assignment. Amendment 1 descoped the LOE associated with specific activities associated with Tasks 2.3, 2.4, 2.5 and 2.6 because, at the time amendment 1 was submitted, the management review of the deliverable would not have been completed by the end of the period of performance (June 30, 2016). With the recent development of the two month extension to the period of performance and the potential for the management review to be completed in that timeframe, this amendment replaces the de-scoped LOE. There are no new tasks and all existing tasks are the same. Unless specifically mentioned here, the other language contained in the original work assignment still applies (e.g., Information Quality Guidelines, QA section, etc.). The contractor shall submit a revised cost estimate within 5 days after receipt of this amendment.

Quality Assurance: The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP (date: March 2012). Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment.

General Requirements of the Work Assignment and Schedule:

<u>Due Dates</u>: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

<u>Delays</u>: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

<u>Draft Documents</u>: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. WACOR will provide comments on draft submissions prior to submission of final documents.

<u>Final Documents</u>: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Milestone/Deliverable Table

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and QA		
Information Quality Guidelines	1.2	Discuss with WACOR within 10 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
Task 2: General Project Support		

Project Planning and Management	2.1	This task is ongoing.
Project Communications Support	2.2	After the workplan approval, throughout the period of performance. Other communication materials will be dependent on the analytical results.
QMRA TSG: QMRA Framework	2.3	Include as part of Volume A
QMRA TSG: Vol A	2.4	Respond to mgmt. comments – in conjunction with WACOR -1 week after receiving mgmt comments and approval.
QMRA TSG: Vol B	2.5	Same schedule as Vol A.
QMRA TSG: Vol C	2.6	Vol C mainly consists of reports prepared individually under other tasks - refer to those tasks for component schedules. Respond to reviewer comments as needed. For supplemental text expanding on those reports: same schedule as Vol A.
Support for SCCWRP study	2.7	Provide QMRA related planning, scoping, analysis, interpretation, and site-specific standard derivation support. Attend workgroup meetings at SCCWRP approximately once per year. Ongoing low level of effort throughout the period of performance.
Task 3: QMRA Anchoring		
Marine NEEAR reverse QMRA	3.1	COMPLETE
Marion anchoring QMRA	3.2	Update report based on EPA and OSU comments and other analyses, within 1 week of receiving EPA comments. Updated draft will be reviewed by HECD management. Mgmt comments will be addressed and final report to be submitted for peer review within 2 weeks of receiving

		comments from management.
Boqueron QMRA	3.3	Additional QMRA analyses using data collected as part of Boqueron health studies. Draft problem formulation submitted in 2015. Contractor shall continue to apply the analytical approach based on technical direction from the WACOR.
QMRA Communications Support	3.4	Non-technical, policy oriented communication materials to support primary deliverables, within 1 week of sending primary deliverable. Materials for general audiences due date to be determined by technical direction.
Task 4: Relative QMRA refinement		
Evaluating sources and receptor locations	4.1	Ongoing throughout the period of performance. Periodic teleconference calls (e.g., bimonthly) with HECD, ICF, and ORD-Athens. Deliverables for this task include notes of teleconference meetings and synopses of modeling developments and capabilities used for internal communication.
Refinement of QMRA analyses of mixed fecal sources	4.2	Low LOE effort throughout the period of performance.
Task 5: Primary and Secondary Contact		
Communications support		Low LOE effort; as needed throughout the period of performance.
Task 6: Sensitive Subpopulations and alternate study designs		
Alternative epidemiology study design	6.2	Low LOE effort; continue efforts to identify RCT data sets.
Task 7: CAWS QMRA support		
Update draft QMRA addressing EPA comments and inclusion of additional questions/information.	7.1	COMPLETE

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Performance Work Statement ICF Contract # EP-C-11-005 Work Assignment #5-04 Amendment 3

Title: QMRA Activities to Support Criteria Development and Implementation

Work Assignment Contracting: John Ravenscroft (Mail Code 4304T)

Officer Representative (WACOR) Office of Water, Office of Science and Technology

Health and Ecological Criteria Division

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Health and Ecological Criteria Division

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Washington, DC 20460 Telephone #: 202-566-0740 E-mail: nappier.sharon@epa.gov

Contractor PWS: 3.1, 3.3, and 3.6

Period of Performance: WA Amendment Issuance through September 30, 2016

**Note: No CBI data will be needed in the course of this work assignment.

Purpose of Amendment: The purpose of this amendment is to add additional LOE for the continued support of existing activities under this work assignment. There are no new tasks and all existing tasks are the same. Unless specifically mentioned here, the other language contained in the original work assignment still applies (e.g., Information Quality Guidelines, QA section, etc.). The contractor shall submit a cost estimate within 5 days after receipt of this amendment.

Quality Assurance: The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP (date: March 2012). Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment.

General Requirements of the Work Assignment and Schedule:

<u>Due Dates</u>: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

<u>Delays</u>: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

<u>Draft Documents</u>: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.

<u>Final Documents</u>: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Milestone/Deliverable Table

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and QA		
Workplan	1.1	Due 5 calendar days after receipt of work assignment
Information Quality Guidelines	1.2	Discuss with WACOR within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
Task 2: General Project Support		
Project Planning and Management	2.1	This task is ongoing.
Project Communications Support	2.2	After the workplan approval, throughout the period of performance, other communication materials will be dependent on the analytical results.

QMRA TSG: QMRA Framework		Include as part of Volume A		
QMRA TSG: Vol A		Respond to mgmt. comments – in conjunction with EPA COR – 1 week after receiving Mgmt comments and approval.		
QMRA TSG: Vol B	2.5	Same schedule as Vol A.		
QMRA TSG: Vol C	2.6	Vol C mainly consists of reports prepared individually under other tasks - refer to those tasks for component schedules. Respond to reviewer comments as needed. For supplemental text expanding on those reports: same schedule as Vol A.		
Support for SCCWRP study	2.7	Provide QMRA related planning, scoping, analysis, interpretation, and site-specific standard derivation support. Attend workgroup meetings at SCCWRP approximately once per year. Ongoing low level of effort throughout the period of performance.		
Task 3: QMRA Anchoring				
Marine NEEAR reverse QMRA	3.1	Task is complete.		
Marion anchoring QMRA	3.2	Update report based on EPA and OSU comments and other analyses, within 1 week of receiving EPA comments. Updated draft will be reviewed by HECD management. Mgmt comments will be addressed and final report to be submitted for peer review within 2 weeks of receiving comments from management.		
Boqueron QMRA	3.3	Additional QMRA analyses using data collected as part of Boqueron health studies. Draft problem formulation submitted in 2015. Contractor shall continue to apply the analytical approach based on technical direction from the EPA COR.		

QMRA Communications Support	3.4	Non-technical, policy oriented communication materials to support primary deliverables, within 1 week of sending primary deliverable. Materials for general audiences due date to be determined by technical direction.
Task 4: Relative QMRA refinement		
Evaluating sources and receptor locations	4.1	Ongoing throughout the period of performance. Periodic teleconference calls (e.g., bimonthly) with HECD, ICF, and ORD-Athens. Deliverables for this task include notes of teleconference meetings and synopses of modeling developments and capabilities used for internal communication.
Refinement of QMRA analyses of mixed fecal sources	4.2	Low LOE effort throughout the period of performance.
Task 5: Primary and Secondary Contact		
Communications support		Low LOE effort; as needed throughout the period of performance.
Task 6: Sensitive Subpopulations and alternate study designs		
Alternative epidemiology study design	6.2	Low LOE effort; continue efforts to identify RCT data sets.
Task 7: CAWS QMRA support		
Update draft QMRA addressing EPA comments and inclusion of additional questions/information.	7.1	Task is complete.

EF	United !	United States Environmental Protection Agency Washington, DC 20460 Work Assignment				Work Assignment Number 5-07 Other Amendment Number:				
Contract Number Contract Period 01/01/2011 το 06/30/20 EP-C-11~005 Post Post Attractor F					2016	.6 Title of Work Assignment/SF Site Name Children's Risks from Fecal				
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Work Assignment Ma	anager Name	John Ravens	croft			Bran	Branch/Mail Code:			
						Pho	Phone Number: 202-566-1101			
(Signature) (Date)						FAX	FAX Number.			
Project Officer Name Shirley Harrison					3-31	Branch/Mail Code:				
						Pho	Phone Number: 202-566-1107			
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Other Agency Official Name Shirley Harrison					W	Branch/Mail Code:				
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(Signature) (Date)							FAX Number:			
Contracting Official Name Noelle Mills							Branch/Mail Code:			
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Performance Work Statement ICF Contract EP-C-11-005 Work Assignment # 5-07

Title: Children's risks from fecal contamination in recreational water

Period of Performance: Work Assignment Issuance through June 30, 2016

Work Assignment Contracting Officer Representative (WACOR):

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**Note: No CBI data will be needed in the course of this work assignment; not subject to FITARA

Contractor SOW: 3.1, 3.3, 3.6

<u>Goal:</u> The overall goal of this performance work statement (PWS) is to examine multiple lines of evidence Center for Disease Control (CDC) Recreational Water Illness outbreak data, risk assessment analyses and epidemiological data) to evaluate the potential that children have disproportionate risks of waterborne illness from recreational water contact.

Objectives:

- 1. Produce a comprehensive report for internal EPA evaluation detailing the known health information for children's waterborne illnesses from recreational water exposure. The report shall demonstrate an evaluation of the scientific literature, risk analysis (e.g., QMRA) and observational results (e.g., National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) study reports).
- 2. Produce a draft and final report for external scientific peer review based on the

- information covered in objective 1.
- 3. Produce communications materials to accompany reports including: a 1 to 2 page nontechnical synopsis, a technical summary document written in non-academic style for a non-scientific audience, a 'questions and answers' (Q&As) document covering areas of potential inquiry from nontechnical and technical audiences (both internal and external), and others as determined by the EPA WAM via technical direction.

Background: A growing body of scientific knowledge has demonstrated that children may suffer disproportionately from environmental health risks and safety risks. These risks occur because 1) children's neurological, immunological, digestive, and other bodily systems are still developing; 2) children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults; 4) children's size and weight may diminish their protection from standard safety features; and 5) children's behavior patterns may make them more susceptible to accidents because they are less able to protect themselves.

The importance of identifying and assessing risks to children was made in Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risk¹, which states:

"to the extent permitted by law and appropriate, and consistent with the agency's mission, each Federal agency:

- (a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and (b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks.
- 1-102. Each independent regulatory agency is encouraged to participate in the implementation of this order and comply with its provisions."

The U.S. Environmental Protection Agency (EPA)'s Policy on Evaluating Risks to Children²:

"considers the risks to infants and children consistently and explicitly as a part of risk assessments generated during its decision making process, including the setting of standards to protect public health and the environment. To the degree permitted by available data in each case, the Agency will develop a separate assessment of risks to infants and children or state clearly why this is not done for example, a demonstration that infants and children are not expected to be exposed to the stressor under examination."

¹ Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks. http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_executiv.htm

² Policy on Evaluating Health Risks to Children, http://www.epa.gov/osa/spc/pdfs/memohlth.pdf

The US EPA's Office of Children's Health Protection³ conducts research and supports risk assessments to assess children's risks and susceptibility to environmental contaminants (chemicals, toxins, air pollutants). However, it not clear whether children suffer disproportionate exposures and health outcomes as a result of exposure to pathogens such as found in recreational surface waters. Few epidemiological data and quantitative risk assessments have explored children's risks from microbial contaminants found in water, limiting the ability to determine if children experience different responses to waterborne fecal indicators and pathogens, or develop illness rates as a result of recreational water contact in the United States. Risks in children have specifically not been explored separately, but they are included as part of the general populations in most epidemiological studies.

Under the auspices of the Clean Water Act, the Agency regulates recreational water, and sets numeric indicator bacteria criteria (*Escherichia coli*, Enterococci) in surface (ambient) waters used for the purpose of recreational water contact. EPA issued new CWA 304(a) recreational ambient water quality criteria in December 2012. The science underpinned the new criteria describes human health effects and water quality studies conducted in waters impacted primarily by human sources of fecal contamination. EPA would like to better understand the risks posed to children associated with recreational exposures. This work assignment covers efforts to develop and disseminate the current understanding in this area.

Task Knowledge and Skills Required: The contractor shall have expertise in preparing the materials associated with this work assignment and be knowledgeable with the various fields of discipline discussed. The contractor shall also be proficient in R programming and other relevant statistical tools. The contractor shall have practical experience in environmental microbiology, epidemiology, and statistical methods and analysis and have advanced credentials in statistics or environmental engineering. The contractor shall be familiar with the different programs under the CWA, use of water quality monitoring, determination of human exposure to environmental contaminant sources, and gastrointestinal (or other) disease endpoints, applications of epidemiological data, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development.

The contractor shall also be able to communicate the study outcomes and recreational outbreak data to a non-technical audience.

Quality Assurance: The tasks in this PWS require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP (date: March 2012). Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

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³ The Office of Children's Health Protection. http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe executiv.htm

The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance (QA) requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment.

<u>Performance Work Statement (PWS)</u>: The scope of this PWS will fall under the following tasks:

Task 1: Work Plan and monthly progress reports (MPR)

Task Area 1.1. Work Plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task Area 1.2. Monthly Progress Reports

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoiced LOE and costs delineated by the tasks in this WA. The contractor shall provide the WACOR with weekly updates detailing progress. The updates shall be provided every Friday via email.

Travel: No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

Task Area 1.3. Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The WACOR will provide the checklist to the contractor. The contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The contractor shall provide the memo at the time it delivers the Final Report under Task 2.1. As requested by the WACOR, the contractor shall have a

teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the checklist.

Task Area 2: Project Reports

Task Area 2.1. Preparation of EPA report detailing results

The contractor prepared and submitted a draft report for EPA technical review under this Task in the previous contract year detailing the information collected and analyzed for the evaluation of human health risks to children from recreational exposure to fecal contamination. EPA comments were given to the contractor and the report was being revised at the close of the previous contract year.

The contractor shall revise the report based on the comments submitted by the WACOR and discuss options for addressing the comments with EPA. The contractor shall also coordinate efforts under this task with the efforts under work assignment 5-14, which may need to incorporate children's health considerations as part of the deliverable. The contractor shall ensure that no duplication of effort occurs, such as searching the scientific literature or evaluating sensitive subpopulations. The contractor shall also prepare effective communication materials to accompany the draft report for use in internal and eventually external communication efforts (see Task 3).

The report may undergo multiple edits and the contractor is expected to respond to EPA comments. This document will need to be formatted as directed by the WACOR. The contractor shall incorporate comments on any draft deliverables from the WACOR. Also, the contractor shall update information in the report as needed to capture any developments related to ongoing studies. The report shall be compliant with Section 508 of the Rehabilitation Act when finalized and submitted (see http://www.epa.gov/accessibility/index.htm).

The contractor submitted a draft report to EPA and received comments from EPA reviewers in option year 3. The contractor incorporated comments and revised the report to facilitate work on Task 2.2.

Task Area 2.2. Preparation of Report of External Scientific Peer Review

The contractor shall prepare and submit a version of the final report based on the deliverable under Task 2.1 that would be suitable for external scientific peer review. This task is subsequent to task 2.1. The contractor shall submit a draft to the WACOR for Agency clearance. When all Agency comments have been addressed, that version may be submitted for peer review. The venue for the peer review is currently undetermined. The contractor shall address peer reviewer comments in conjunction with the WACOR. This document will need to be formatted for publication as directed by the WACOR.

Travel: No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

Task Area 3: Communication materials

As specified in the above methodology section, the contractor shall prepare, in conjunction with the WACOR, materials to assist in communicating the complex technical aspects of the project results to both non-technical and technical (but not academic) audiences (both internal and external to the Agency). These materials will most likely consist of synopses, executive summaries, Q&As, presentation slides, etc. and each may be aimed at a particular audience or to tailored for the communication need. The contractor shall coordinate with the WACOR on the scope and nature of these materials for specific audiences.

Task Area 4: General Project Support

The contractor shall, based on technical direction given by the WACOR, provide support in preparing interim project update sand/or other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractor may be requested to participate in and/or conduct briefings and/or present at meetings. It is estimated that this task should not require more than 5-10% of the total LOE allotted to this work assignment.

One of the outcomes of the project planning meeting detailed in Task 2.1 may be the identification of data or analysis gaps, particularly in regards to the QMRA analysis. For example, the finalized analysis of the NEEAR marine data was not completed at the time of the conduct of the QMRA under B-04, task 6. Although the final analysis of that data did not show a significant difference in illness response between children 12 and under and the general population, using this combined dataset may be helpful for the discussion of the QMRA portion of the deliverables under tasks 2.1 and 2.2. Should such analyses be identified as important based on the outcome of the project planning meeting, the WACOR will provide technical direction to ICF.

The contractor shall plan on attending one presentation at EPA HQ at the draft report stage to discuss findings. All appropriate clearances and approvals required by Agency policy in support of any and all meetings shall be obtained by the EPA COR as needed and provided to the Contracting Officer. Work under meeting-related activities and expenses shall not occur until this approval is obtained and provided by the CL-COR.

Task No.	Milestones/Deliverable*	Schedule
1	1.1 Workplan	Per contract requirements
1	1.3 Information Quality Guidelines	Submitted with final
	50 AB	deliverables
2	*2.1 Draft report for EPA review	Draft submitted
2	2.1 Respond to EPA reviewer comments	Task in progress during
		final quarter of 2015
2	2.1 Submit final report to EPA	Within 2 weeks of
	=	addressing comments
2	2.2Submit draft report for EPA review	TBD based on outcome of

		Task 2.1
2	2.2 Respond to EPA reviewer comments	Within 2 weeks of
		receiving EPA comments
2	2.2 Submit final report to EPA for peer	Within 2 weeks of
	review clearance	addressing comments
3	Prepare risk communication presentation	TBD by technical
	materials for technical and non-technical	direction
	audiences	
4	General project support	TBD by technical
	and the second s	direction

^{*} Report was on schedule to be submitted to EPA by the end of previous contract year when this work assignment was being prepared. The milestone was included here to provide a starting point for Task 2 activities.

General Requirements of the Work Assignment and Schedule:

<u>Due Dates</u>: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

<u>Delays</u>: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

<u>Draft Documents</u>: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. WACOR will provide comments on draft submissions prior to submission of final documents.

<u>Final Documents</u>: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Technical Direction:

The COR or an authorized individual is permitted to provide technical direction. Technical direction must be within the statement of work of the contract and includes: (1) Direction to the contractor which assists the contractor in accomplishing the Statement of Work, (2) Comments on and approval of reports or other deliverables. Technical direction will be issued in writing or confirmed in writing within five (5) calendar days after verbal issuance. One copy of the technical direction memorandum will be forwarded to the Contracting Officer and the Contracting Officer Representative.

Contractor Identification:

Contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, Contractor personnel shall wear a badge which identifies the individual as a contractor employee. Contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

Confidentiality:

Some of the work assigned under these tasks will be to draft, edit and review sensitive program and organizational information. The contractor shall not discuss the contents of the conference or meeting discussions with anyone that did not participate in those discussions.

Notice Regarding Guidance Provided under this Work Assignment:

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the EPA COR or the EPA Contracting Officer.

References

CDC Rec Water Outbreaks:

Alphabetical index of Water-Related Health Data:

http://www.cdc.gov/healthywater/statistics/surveillance/health_data.html

CDC Healthy Swimming Webpage: http://www.cdc.gov/healthywater/swimming/data/

Epidemiological studies:

"High Sensitivity of Children to Swimming-Associated Gastrointestinal Illness Results Using a Rapid Assay of Recreational Water Quality" Timothy J. Wade, Rebecca L. Calderon, Kristen P. Brenner, Elizabeth Sams, Michael Beach, Richard Haugland, Larry Wymer, and Alfred P. Dufour (Epidemiology 2008;19: 375–383) http://journals.lww.com/epidem/Abstract/2008/05000/High_Sensitivity_of_Children_to.8 asspx

Marine Studies (P1, 2):

"Rapidly measured indicators of recreational water quality and swimming-associated illness at marine beaches: A prospective cohort study" Timothy J Wade, Elizabeth Sams, Kristen P Brenner, Rich Haugland, Eunice Chern, Michael Beach, Larry Wymer, Clifford C Rankin, David Love, Quanlin Li, Rachel Noble and Alfred P Dufour - Environmental Health 2010, 9:66doi:10.1186/1476-069X-9-66 Published: 31 October 2010

• Table S2: Adjusted Odds Ratios for illness risk among swimmers for a 1 log10 Increase in indicator density. Children age 10 and under. http://www.ehjournal.net/imedia/3968942414721357/supp2.pdf Epidemiological study in marine waters impacted by urban runoff in a temperate region $(CD \ 5(a))$:

"Report on 2009 National Epidemiologic and Environmental Assessment of Recreational Water Epidemiology Studies" Timothy J Wade, Elizabeth A Sams, Rich Haugland, Kristen P Brenner, Quanlin Li, Larry Wymer, Marirosa Molina, Kevin Oshima and Alfred P Dufour. US Environmental Protection Agency, Office of Research and Development; 2010.USEPA Report Number: EPA/600/R-10/168.

- Table 4.5, 4.6: Water exposures among children
- Tables 4.8-4.12: Incidence of illness among children
- Table 4.39, 4.42, 4.56, 4.57,
- Figure 5.16: Incidence of illness among children with regard to measures of water quality.

http://water.epa.gov/scitech/swguidance/waterquality/standards/criteria/health/recreation/index.cfm

Epidemiological study in a tropical region (CD 5(b)):

"Report on 2009 National Epidemiologic and Environmental Assessment of Recreational Water Epidemiology Studies" Timothy J Wade, Elizabeth A Sams, Rich Haugland, Kristen P Brenner, Quanlin Li, Larry Wymer, Marirosa Molina, Kevin Oshima and Alfred P Dufour. US Environmental Protection Agency, Office of Research and Development; 2010.USEPA Report Number: EPA/600/R-10/168.

Wade, T. J., R. L. Calderon, et al. (2006). "Rapidly measured indicators of recreational water quality are predictive of swimming-associated gastrointestinal illness." Environ Health Perspect 114(1): 24-8.

Wade, T. J., N. Pai, et al. (2003). "Do U.S. Environmental Protection Agency Water Quality Guidelines for Recreational Waters Prevent Gastrointestinal Illness? A Systematic Review and Meta-analysis." Environmental Health Perspectives 111(8): 1102-1109.

Colford, J. M., Jr., T. J. Wade, et al. (2007). "Water Quality Indicators and the Risk of Illness at Beaches With Nonpoint Sources of Fecal Contamination." Epidemiology 18(1): 27-35.

Fleisher, J. M., F. Jones, et al. (1993). "Water and non-water-related risk factors for gastroenteritis among bathers exposed to sewage-contaminated marine waters." International Journal of Epidemiology 22(4): 698-708.

Fleisher, J. M., D. Kay, et al. (1996). "Marine waters contaminated with domestic sewage: nonenteric illnesses associated with bather exposure in the United Kingdom." Am J Public Health 86(9): 1228-34.

Kay, D., J. M. Fleisher, et al. (1994). "Predicting likelihood of gastroenteritis from sea bathing: results from randomised exposure." Lancet 344(8927): 905-9.

Wiedenmann, A., P. Kruger, et al. (2006). "A randomized controlled trial assessing infectious disease risks from bathing in fresh recreational waters in relation to the concentration of Escherichia coli, intestinal enterococci, Clostridium perfringens, and somatic coliphages." Environ Health Perspect 114(2): 228-36.

Kay, D., N. Ashbolt, et al. (2006). "Reply to comments on "Derivation of numerical values for the World Health Organization guidelines for recreational waters"." Water Res 40(9): 1921-5.

Kay, D., J. Bartram, et al. (2004). "Derivation of numerical values for the World Health Organization guidelines for recreational waters." Water Res 38(5): 1296-304.

A description of EPI-BATHE can be found: http://www.aber.ac.uk/iges/research/epibathe/favorite.htm

Manager's Planning Checklist for Peer Review

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2) What Decision/Rule/Regulation/Action Does this Work Product Support:

Support for development and implementation of ice ANDL.

3) Designation of Scientific and Technical Work Products

- O is the work product scientific or technical __yes __no?
- O Is the work product __influential scientific information (ISI), __highly influential scientific assessment (IBSA), or __other? (See Section 2.2.3 and 2.2.4 of the Peer Review Hardbook for an explanation of these terms).

4) Determining What Peer Review is Needed

- C If ISI or IHSA, peer review is needed.
- G. If not influential, is peer review still needed?
- G. What peer review mechanism is needed (internal and/or external)?
- G. When does the review need to be done?
- G. How much time will be needed to conduct/complete the review?
- (3) Are there court ordered deadlines or other constraints?
- G. Has senior management (AA/RA/others) been informed of progress/problems?
- G. What would constitute success for this review?

5) Determining the Resources for Peer Review

- G. What is the priority of this project relative to other projects in the same office?
- G. What resources are needed to conduct the review?
- G. What are the impacts of the review on personnel?
- G. Who will lead the peer review?
- G. Who will conduct the peer review?
- 6 Who will maintain the peer review record?
- C. Where will the peer review record be kept?
- G. What mechanism will be used for the peer review?
- 6 I las the charge been developed?
- 5: Has internal and external conraination been initiatec/completed?
- Have arrangements for interins/final sign offs (e.g., for the charge, the punel, on any changes to the final work product) been made?
- 3 How will results of the review be presented and addressed in the final work product (e.g., in a preamble, to an accompanying appendix as well as changes in the work product itself)?
- If I fas the work product been entered into the Science Inventory):

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PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-11-005 **WORK ASSIGNMENT #5-08**

Title: Activities to support the development of Ambient Water Quality Criteria for **Pathogens**

Work Assignment Contracting Officer Representative (WACOR):

Sharon Nappier (Mail Code 4304T) Health and Ecological Criteria Division Office of Water, Office of Science and Technology 1200 Pennsylvania Avenue, N.W. Washington, DC 20460

Phone (202) 566-0740

E-mail: nappier.sharon@epa.gov

Alternate WACOR: John Ravenscroft (Mail Code 4304T)

Health and Ecological Criteria Division

Office of Water, Office of Science and Technology

1200 Pennsylvania Ave, N.W.

Washington, DC 20460 Phone (202) 566-1101

E-mail: <u>ravenscroft.john@epa.gov</u>

Period of Performance: January 1, 2016 thru June 30, 2016

Contractor SOW: 3.1, 3.3, 3.4, 3.6

**Note: No CBI data will be needed in the course of this work assignment.

Background:

Human health ambient water quality criteria (AWQC) are numeric values limiting the amount of chemical or microbial agents present in our nation's waters. Human health criteria are developed under Section 304(a) of the Clean Water Act of 1972 and are designed to protect human health. Water quality criteria are developed by assessing the relationship between pollutants and their effect on human health and the environment. These criteria are used by states and Indian tribes to establish water quality standards and ultimately provide a basis for controlling discharges or releases of pollutants.

EPA has published AWQC for bacteria. Historically EPA has based the bacteria criteria on fecal indicator bacteria (FIB). These organisms do not generally cause human illness themselves (that is, they are not human pathogens); rather, they are indicators of fecal contamination and therefore indicators of the potential presence of human pathogenic organisms.

The EPA is now interested in creating AQWC for viruses. EPA believes that these virus criteria must be scientifically sound, implementable for broad CWA purposes, and provide for improved public health protection.

Quality Assurance:

The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved contract-level QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment.

Statement of Work: The scope of work in this assignment will fall under the following task areas:

Task 1: Work plan and monthly progress reports

Task 1.1 Work Plan

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the WACOR via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task 1.2 Monthly Progress Reports

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are

expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.3 Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The WACOR will provide the checklist to the contractor. The contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the checklist.

TASK 2 – Literature Reviews

Task Area 2.1 Bacteriophage Literature Review

Task Completed

This task is a continuation of previous efforts to conduct a bacteriophage literature review to identify important research that support the development of future bacteriophage criteria. The bacteriophage literature review has undergone peer-review. The contractor shall assist in incorporating comments and edits and deliver a final literature review product. At EPA's direction, the contractor shall make the final document 508 compliant.

TASK 3 – Ambient Water Quality Criteria Coliphages and other Viruses

Task Area 3.1 Scope of the Criteria Documents

This task will require the contractor to assist scoping the AWQC for Viruses for recreational designated uses. Viruses of immediate interest include, but are not limited to, bacteriophage, norovirus, adenovirus, and enterovirus. EPA is considering one criterion document for coliphage and another for pathogenic viruses, such as enteroviruses and noroviruses. Under this task area, the contractor shall assist in drafting an outline of pathogen criteria for viral indicators and pathogenic viruses and identifying the needs of the criterion documents.

Task Area 3.2 Derivation of the Criteria Values

This task is a continuation of earlier efforts to use risk assessment and other statistical methods to develop AWQC values for the viruses of interest. Through Technical Direction by the WACOR, the contractor shall develop AWQC values to be used in future criteria for coliphage and potentially other viruses.

Task Area 3.3 Develop Criterion Document Drafts

The contractor shall provide draft documents of the AWQC for viruses. Specific viruses and the order of importance will be provided through Technical Direction. This task will be an ongoing effort for the period of performance of this work assignment and a series of Drafts are expected.

Task Area 3.4 Prepare and submit Final AWQC Criteria for Coliphage and other Viruses

The contractor shall prepare and submit a Final RWQC document. This document will need to be 508 Compliant and formatted as directed by the WACOR.

Task Area 3.5 Prepare briefing materials and other supporting documents pertaining to the Virus Criteria documents

Briefing materials and other supporting documents will be needed during the Criteria development process. The contractor shall aid the in the development of any materials or presentations for these purposes.

Task Area 4 - General Project Support

The contractor shall, based on technical direction given by the WACOR, provide support in preparing interim project update and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractor may also be directed to participate in and/or conduct briefings. A weekly update call with the WACOR will be required for this work assignment, as needed.

Some meetings may require contractor support and/or attendance for note-taking, presentations, and meeting preparation materials. Details on travel dates and locations will be provided by the WACOR through technical direction, as further information becomes available.

Travel: Travel may be needed as deemed necessary by the WACOR. This PWS will provide travel funds for up to eight trips for contractor and/or subcontractors to travel to Washington DC and to conferences, which may include, but are not limited to, the 2016 Beach Conference (April 12-15) in New Orleans, LA and the Water Microbiology Conference 2016 (May 17-19) in Chapel Hill, NC.

Task 5 - Planning and Supporting an Experts Science Workshop

The contractor shall, based on technical direction given by the WACOR, provide support in preparing, planning, and executing an Experts Science Workshop for the development of Ambient Water Quality Criteria for Coliphage. Planning activities may include, but are not limited to: designing the expert workshop agenda; developing, compiling and distributing pre-meeting and meeting materials; attending pre-meeting phone calls; selecting meeting participants; communicating logistics with attendees; and reserving a hotel block.

At the meeting, the contractor support activities will include, but are not limited to: presenting materials, meeting facilitation; note-taking, setting up a registration desk; and preparing the packet of materials for attendees, name tags, tent cards, and travel reimbursement forms. The contractor shall provide a facilitator and up to three note-takers for the Experts Workshop.

Task 6 - Fact Sheet and Meetings Proceedings Report

At the end of the workshop, the contractor shall review and organize notes; develop a fact-sheet on key points of the meeting; and write a Meetings Proceedings Report. Both the fact-sheet and Meeting Proceedings Report (Pre peer-review Draft and Final) will need multiple reviews and drafts.

Fact Sheet: The contractor shall provide a design for the fact-sheet. The DRAFT fact-sheet will be provided to the WACOR no later than 2 weeks after the Experts Science Workshop. The Fact Sheet will need multiple reviews and drafts. The contractor shall incorporate changes and comments into the Fact Sheet.

Meeting Proceedings Report: The contractor shall frame the chapters and provide a DRAFT outline of the Meeting Proceedings Report to the WACOR no later than 2 weeks after the Experts Science Workshop. The Meeting Proceedings Report will be a compilation of the notes taken at the Workshop. A compilation of the notes into the Report outline will be provided to the WACOR no later than 1 month after the Experts Science Workshop. The Meetings Proceedings Report will need multiple reviews and drafts. The contractor shall incorporate changes and comments into the Report.

The Meetings Proceedings Report will be independently peer-reviewed. Thus, there will be a Peer-Review Draft version and a Final version that will be published by EPA. The contractor shall ensure the Final Fact Sheet and the Final Meetings Proceedings Report version are 508 compliant.

Details on travel dates and locations for the Experts Science Workshop will be provided by the WACOR through technical direction, as further information becomes available.

Travel: Travel will be necessary. This PWS will provide travel funds for up to 15 sub-contractors and/or subject matter experts. Through technical direction of the WACOR, the contractor shall help make travel arrangements for sub-contractors and subject matter experts.

Task No.	Deliverable	Schedule
1	1.1 Work Plan	Within 10 business days of receipt of WA
Ī	1.2 Monthly Progress Reports	Per contract requirement
2	3.1 Bacteriophage Literature Review ~ FINAL - 508 Compliant	COMPLETED
3	4.1 Scope of the Criteria documents	TBD
3	4.2 Derivation of the Criteria Values	TBD
3	4.3 Develop Criteria Document Drafts	TBD
3	4.4 Submit Final AWQC Criterion for Viruses	TBD
3	4.5 Prepare briefing materials and other supporting documents	TBD
-1	5.0 General Project Support	TBD
5	Experts Workshop Agenda	TBD
5	Experts Workshop Pre- meeting Materials	TBD
5	Experts Workshop Meeting Materials	TBD
6	Experts Workshop Fact Sheet - DRAFT	Two weeks after the Experts Workshop concludes
6	Experts Workshop Fact Sheet – FINAL (508 compliant)	Two weeks after receipt of draft from WACOR
6	Experts Workshop – Meeting Proceedings Report – DRAFT	Four weeks after the Experts Workshop concludes
6	Experts Workshop – Meeting Proceedings Report – DRAFT for Peer-Review	Two weeks after receipt of draft from WACOR
6	Experts Workshop – Meeting Proceedings Report – Post- Peer Review DRAFT	Two weeks after receipt from WACOR (post peer-review)
6	Experts Workshop – Meeting Proceedings Report – Post- Peer Review DRAFT (508 compliant)	TBD

Quality Assurance: Tasks 2-4 in this work assignment require the use of secondary data. An approved project-specific QAPP has already been approved, under B-08.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Knowledge and Skills Required:

The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology and/or environmental engineering. The contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints.

General Requirements of the Work Assignment and Schedule:

<u>Due Dates</u>: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

<u>Delays</u>: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

<u>Draft Documents</u>: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.

<u>Final Documents</u>: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Meetings, Conferences, Training Events, Award Ceremonies and Receptions:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA Contract Level Contracting Officer Representative (COR) as needed and provided to the contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA COR.

Technical Direction:

The COR or an authorized individual is permitted to provide technical direction.

Technical direction must be within the statement of work of the contract and includes:

(1) Direction to the contractor which assists the contractor in accomplishing the Statement of Work, (2) Comments on and approval of reports or other deliverables.

Technical direction will be issued in writing or confirmed in writing within five (5) calendar days after verbal issuance. One copy of the technical direction memorandum will be forwarded to the Contracting Officer and the Contracting Officer Representative.

Contractor Identification:

Contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, Contractor personnel shall wear a badge which identifies the individual as a contractor employee. Contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

Confidentiality:

Some of the work assigned under these tasks will be to draft, edit and review sensitive program and organizational information. The contractor shall not discuss the contents of the conference or meeting discussions with anyone that did not participate in those discussions.

Notice Regarding Guidance Provided under this Work Assignment:

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the EPA COR or the EPA Contracting Officer.

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PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-11-005 WORK ASSIGNMENT #5-08 Amd 1

Title: Activities to support the development of Ambient Water Quality Criteria for Pathogens

Work Assignment Contracting Officer Representative (WACOR):

Sharon Nappier (Mail Code 4304T)
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Washington, DC 20460
Phone (202) 566-0740

E-mail: nappier.sharon@epa.gov

Alternate WACOR: John Ravenscroft (Mail Code 4304T)

Health and Ecological Criteria Division

Office of Water, Office of Science and Technology

1200 Pennsylvania Ave, N.W.

Washington, DC 20460 Phone (202) 566-1101

E-mail: ravenscroft.john@epa.gov

Period of Performance: Work Assignment Amendment thru August 31, 2016

Contractor SOW: 3.1, 3.3, 3.4, 3.6

**Note: No CBI data will be needed in the course of this work assignment.

Purpose of Amendment: The purpose of this work assignment amendment is to provide additional LOE to support efforts related to the development of Recreational Water Quality Criteria for Coliphage. *Task 3 thru Task 6 remain the same, no change).* The contractor shall submit a revised cost estimate within 5 days after receipt of this amendment.

Task No.	Deliverable	Schedule
2	3.1 Bacteriophage Literature	COMPLETED
	Review – FINAL – 508	
	Compliant	
3	4.1 Scope of the Criteria	TBD
	documents	
3	4.2 Derivation of the Criteria	TBD
	Values	
3	4.3 Develop Criteria	TBD
	Document Drafts	

3	4.4 Submit Final AWQC	TBD
3	the same of the sa	IBD
	Criterion for Viruses	
3	4.5 Prepare briefing materials	TBD
	and other supporting	
	documents	
4	5.0 General Project Support	TBD
5	Experts Workshop Agenda	COMPLETED
5	Experts Workshop Pre-	COMPLETED
	meeting Materials	
5	Experts Workshop Meeting	COMPLETED
	Materials	
6	Experts Workshop Fact Sheet	COMPLETED
	– DRAFT	
6	Experts Workshop Fact Sheet	Two weeks after receipt of draft
	- FINAL (508 compliant)	from WACOR
6	Experts Workshop – Meeting	Four weeks after the Experts
	Proceedings Report – DRAFT	Workshop concludes
6	Experts Workshop – Meeting	Two weeks after receipt of draft
	Proceedings Report – DRAFT	from WACOR
	for Peer-Review	
6	Experts Workshop – Meeting	Two weeks after receipt from
	Proceedings Report – Post-	WACOR (post peer-review)
	Peer Review DRAFT	
6	Experts Workshop – Meeting	TBD
	Proceedings Report – Post-	
	Peer Review DRAFT (508	
	compliant)	

Quality Assurance: The tasks 3-4 in this work assignment require the use of secondary data. An approved project-specific QAPP has already been approved, under B-08.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Knowledge and Skills Required:

Contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The Contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology and/or environmental engineering. The Contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints.

General Requirements of the Work Assignment and Schedule:

<u>Due Dates</u>: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

<u>Delays</u>: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

<u>Draft Documents</u>: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. WACOR will provide comments on draft submissions prior to submission of final documents.

<u>Final Documents</u>: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Attachment 1

QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, statistical data analysis (i.e. statistical analysis & any other types of data analysis), and assumptions/recommendations based on the data analysis, if applicable, shall be included.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0, QUALITY OF SECONDARY DATA

3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if

- applicable. (If appropriate, a related QAPP containing this information can be referenced.)
- 3.2 The procedures for determining the quality of the secondary data shall be described.
- If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

EPA	United States Environm Washing	Work Assignment Number 5-08						
	Work As	ssignment			Other X Amendment Number:			
Contract Number	Contract Period 01/	'01/2011 To	08/31/3	2016	Title of Work Assign:	ment/SF Site Nam	e	
EP-C-11-005	Base	Option Period Nu	mber 5		Activities t			
Contractor			y Section and pa	ragraph of Cor	tract SOW			
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Purpose. Work Assignment		Work Assignment C	Close-Out		Period of Performan	ce		
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X Work Plan Approval	_		_		From 01/01/	2016 ™ 08	/31/2016	
Comments:								
Superfund	Acco	ounting and Appro	priations Data			X	Non-Superfund	
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<u>-</u>	ppriation Budget Org/Code (Max 6) (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (De	illars) (Cents)	Site/Project (Max 8)	Cost Org/Code	
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							-	
Total:	\$299,831.0				2,196			
		rk Plan / Cost Esti	mate Approva	71100				
Contractor WP Dated: 07/11/2016	Cost/Fee \$1	100,253.00		LQE:	835			
Cumulative Approved.	Cost/Fee \$	299,831.00		LOE:	2,196			
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				Phor	e Number: 202-	566-0740		
(Signature)		(Date))		Number:			
Project Officer Name Shirley Harr	ison		-	Bran	ch/Mail Code:			
	Phor	ie Number: 202-5	366-1107					
(Signature)		Number:		_				
Other Agency Official Name					ch/Mail Code:			
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(Signature)		(Dale)			Number:			
Contracting Official Name , Kathleen	Rechemberg			-	ch/Mail Code:			
- Kalkler	Keeherbe	9 7/m	27/16	Phor	e Number: 513-	487-2853		
(Signature)		(Date)	1		Number:			

EPA			ι	United States Environmental Protection Agency Washington, DC 20460					Work Assignment Number 5 – 08				
				Work Assignment					Other X Amendment Number:				
Contract	Number			Contract Pe	riod 01,	/01/2011 To	09/30/2	2016	Title of W	ork Assigni	ment/SF Site Na	ne	
EP-C-	11-00	5		Base		Option Period Nu	mber 5		AWQC for Pathogens				
Contracto	Contractor Specify Section and paragraph of Contract SOW												
ICF 1	ICF INCORPORATED, L.L.C. 3.1,3.3,3.4,3.6												
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		=	lan Approval	ament		Incrementary unam	9		From 01/01/2016 To 09/30/2016				
Commen	ts:								•				
	Superl	fund			Acc	ounting and Appro	priations Data				X	Non-Superfund	
SFO (Max 2) Note: To report additional accounting and appropriations date use EPA Form 1900-69A.													
_	DCN Max 6)	Budget/F (Max 4)			t Org/Code Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (D	ollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code	
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Work Ass	ianment M	lanager Name	Sharon	Nappier				Bra	ranch/Mail Code:				
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Contracti	ng Official	name Ka	ichiteen R	-chemper	A				ranch/Mail Code:				
								hone Number: 513-487-2853					
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PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-11-005 WORK ASSIGNMENT #5-08 Amendment 2

Title: Activities to support the development of Ambient Water Quality Criteria for Pathogens

Work Assignment Contracting Officer Representative (WACOR):

Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740

E-mail: nappier.sharon@epa.gov

Alternate WACOR:

John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101

E-mail: ravenscroft.john@epa.gov

Period of Performance: Work Assignment Amendment thru September 30, 2016

Contractor SOW: 3.1, 3.3, 3.4, 3.6

**Note: No CBI data will be needed in the course of this work assignment.

Purpose of Amendment: The purpose of this work assignment amendment is to provide additional LOE to support efforts related to the development of Recreational Water Quality Criteria for Coliphage. *Task 3 thru Task 6 remain the same, no change*). The contractor shall submit a revised cost estimate within 5 days after receipt of this amendment.

Task No.	Deliverable	Schedule
2	3.1 Bacteriophage Literature	COMPLETED
	Review – FINAL – 508	
	Compliant	
3	4.1 Scope of the Criteria	TBD
	documents	
3	4.2 Derivation of the Criteria	TBD
	Values	

3	4.3 Develop Criteria	TBD
	Document Drafts	100
3	4.4 Submit Final AWQC	TBD
	Criterion for Viruses	TDD
3	4.5 Prepare briefing materials	TBD
	and other supporting	100
	documents	
4	5.0 General Project Support	TBD
5	Experts Workshop Agenda	COMPLETED
5	Experts Workshop Pre-	COMPLETED
	meeting Materials	COMILLIED
5	Experts Workshop Meeting	COMPLETED
	Materials	COMILETED
6	Experts Workshop Fact Sheet	COMPLETED
ľ	- DRAFT	
6	Experts Workshop Fact Sheet	Two weeks after receipt of draft
	- FINAL (508 compliant)	from WACOR
6	Experts Workshop – Meeting	Four weeks after the Experts
	Proceedings Report - DRAFT	Workshop concludes
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	for Peer-Review	
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	Proceedings Report - Post-	WACOR (post peer-review)
	Peer Review DRAFT	
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	Proceedings Report - Post-	
	Peer Review DRAFT (508	
	compliant)	

Quality Assurance: The tasks 3-4 in this work assignment require the use of secondary data. An approved project-specific QAPP has already been approved, under B-08.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Knowledge and Skills Required:

The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology and/or environmental engineering. The contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints.

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<u>Final Documents</u>: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

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- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

	United States Environm	United States Environmental Protection Agency				Work Assignment Number				
l EDA		gton, DC 20460		5-09						
EPA	Work A	ssianment		Other Amendment Number:						
	HOIKA	Work Assignment				Cities Attendation (Manager,				
Contract Number	2016	16 Title of Work Assignment/SF Site Name								
FR-C-11-005					HHA: Cryptos/Giardia					
Contractor	Dase		mber 5 y Section and pa	ragraph of Cor		5/G.aiuia				
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Purpose: X Work Assign	nment	Work Assignment (Close-Qut		Period of Performance					
Work Assign	ment Amendment	Incremental Funding	ng.							
Work Plan A	-		а.		From 01/01/2016 To 06/30/2016					
Comments	pprovai				1		, 00, 2010			
Superfund	Acco	ounting and Appro	priations Data	9		X	Non-Superfund			
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© DON Budge(FY □ (Max 6) (Max 4)	Appropriation Budget Org/Code Code (Max 6) (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (De	ollars) (Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)			
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Cumulative Approved:	Cost/Fee:		LOE.							
Work Assignment Manager Name S	hamima Akhter			Bran	Branch/Mail Code:					
					Phone Number 202-566-1341					
(Signatur	re)	(Date)	1		FAX Number:					
Project Officer Name Shirley Harrison					Branch/Mail Code:					
	11-152/05/07	Phone Number: 202-566-1107								
(Signatur	_	FAX Number:								
Other Agency Official Name Shir		Branch/Mail Code:								
	<u> </u>	Phone Number: 202-566-1107								
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PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-11-005 WORK ASSIGNMENT # 5-09

Title: Human Health Assessment: Cryptosporidium and Giardia in drinking and ambient water

Work Assignment Contracting Officer

Representative (WACOR) Shamima Akhter (Mail Code 4304T)

Health and Ecological Criteria Division

Office of Water, Office of Science and Technology

1200 Pennsylvania Ave, N.W.

Washington, DC 20460 Phone (202) 566-1341

E-mail: akhter.shamima@epa.gov

Alternate WACOR: John Ravenscroft (Mail Code 4304T)

Health and Ecological Criteria Division

Office of Water, Office of Science and Technology

1200 Pennsylvania Ave, N.W.

Washington, DC 20460 Phone (202) 566-1101

E-mail: ravenscroft.john@epa.gov

Period of Performance: January 1, 2016 through June 30, 2016

Contractor SOW: 2.2, 3.1.6, and 3.1.8

Background:

The mission of the U.S. Environmental Protection Agency's (EPA) Office of Water is to protect public health and the environment from adverse effects of pollutants (e.g., toxic chemicals and microbial pathogens) in ambient water, drinking water, wastewater, sewage sludge and sediments. The Safe Drinking Water Act (SDWA) requires the EPA to regulate disease-causing organisms (pathogens) and toxic chemicals in drinking water.

The Safe Drinking Water Act requires the U.S. Environmental Protection Agency (EPA) to publish regulations to control disease-causing organisms (pathogens) and hazardous chemicals in drinking water. One of the regulations published by EPA to control pathogens is known as the Surface Water Treatment Rule (54 FR 27486; June 29, 1989). The purpose of the Long Term 2 (LT2) rule is to reduce illness linked with the contaminant *Cryptosporidim*, *Giardia* and other disease-causing microorganisms in drinking water. Under the LT 2 Rule, *Cryptosporidium* oocysts at or below 0.075 oocysts/liter are considered the maximum value under which conventional drinking water treatment is expected to be capable of providing protection of consumers drinking up to 1.2 liters of water per day. Under the Safe Drinking Water Act's Surface Water Treatment Rule (further referred to as the Rule) *Giardia* cyst Maximum

Contaminant Level Goal (MCLG) levels are set at "0" for treated water. In order to meet this requirement, *Giardia* cyst removal by conventional drinking water treatment must be able to reduce cyst levels by 3 orders of magnitude (3 logs) from source waters to insure protection of consumers drinking up to 2.0 liters of water per day.

Cryptosporidium is a significant concern in drinking water because it contaminates surface waters used as drinking water sources, it is resistant to chlorine and other disinfectants, and it has caused waterborne disease outbreaks. Consuming water with Cryptosporidium. a contaminant in drinking water sources, can cause gastrointestinal illness (e.g., diarrhea, vomiting, cramps) and other health risks, which may be severe in people with weakened immune systems (e.g., infants and the elderly) and sometimes fatal in people with severely compromised immune systems (e.g., cancer and AIDS patients).

Cryptosporidium oocysts are common and widespread in ambient water and can persist for months in this environment. The dose that can infect humans is low, and a number of waterborne disease outbreaks caused by this protozoan have occurred in the U.S., most notably in Milwaukee, where an estimated 400,000 people became ill. The healthy people recover within several weeks after becoming ill, but illness may persist and contribute to death in those whose immune systems have been seriously weakened (e.g., AIDS patients). Drugs effective in preventing or controlling this disease are not yet available. The public health concern is worsened by the resistance of Cryptosporidium to water disinfection practices by chlorination, although oocysts can be inactivated by ozone and ultraviolet irradiation. However, a well-operated water filtration system is capable of removing at least 99 of 100 Cryptosporidium oocysts in the water. Monitoring for this organism in water is currently difficult and expensive.

The purpose of these documents is to serve as informal technical guidance to assist Federal, state, and local officials responsible for protecting public health when emergency spills or contamination situations occur.

Quality Assurance:

The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved contract-level QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the WACOR before activities covered by the additional QA language begin under this work assignment.

Performance Work Statement (PWS):

Task 1: Work plan and monthly progress reports

Task 1.1 Work Plan

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the WACOR via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

Task 1.2 Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The WACOR will provide the checklist to the contractor. The contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report. The contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the checklist.

Task 2: Develop Health Assessment document: Cryptosporidium

2.6 Communication piece

The contractor shall provide a brief communication document (1- 3 pages) which will aid in briefing EPA managers and senior managers. The communication piece shall be written in plain English language for non-technical people and the relevant scientific studies shall be included as an attachment.

2.9 Submit Final Report

Upon the WACOR's approval, the contractor shall send the final revised pcer-reviewed report in Microsoft Word, version 2003 or higher, to the WACOR

Task 3: Develop Health Assessment document: Giardia

3.6 Communication piece

The contractor shall provide a brief communication document (1- 3 pages) which will aid in briefing manager and senior managers. The communication piece shall be written in plain English language for non-technical people and the relevant scientific studies shall be included as an attachment.

3.9 Submit Final Report

Upon the WACOR's approval, the contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the WACOR

Period of Performance/Milestones: It is the Contractor's responsibility to coordinate with the WACOR while conducting these tasks.

Task	Milestone	Date due
1	1.1 Work Plan	Due 15 calendar days after receipt of WA
1	Kick-off meeting with WACOR	1 week after WP approval
2	2.6 Communication Piece	TBD
2	2.9 Submit final report	TBD
3	3.6 Communication Piece	TBD
3	3.9 Submit final report	TBD

Knowledge and Skills Required: The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this PWS. The contractor shall be an accomplished microbial risk assessor with experience in environmental media, especially water. The contractor shall have knowledge and experience with the *Cryptosporidium and Giardia spp.* protozoa in water and water/wastewater treatment/disinfection effectiveness. The contractor shall be experienced in evaluation of data bases, statistics, and modeling regarding human exposure, dose response and health effects for application in microbial risk assessments.

General Requirements of the Work Assignment and Schedule:

<u>Due Dates</u>: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

<u>Delays</u>: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

<u>Draft Documents</u>: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. WACOR will provide comments on draft submissions prior to submission of final documents.

<u>Final Documents</u>: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

<u>Final Documents</u>: The contractor shall revise and incorporate all EPA's comments and submit final documents both electronically and in hardcopy (Microsoft version 2003 or higher) to WACOR. The Agency may decide to publish the report on the web. If this occurs, the report will need to be 508 compliant and the WACOR will provide appropriate technical direction.

<u>Final Peer Reviewed Document</u>: Upon receipt of the EPA's external expert peer-review of the contractor's Final Written Report, the WACOR will provide the contractor with the recommended edits and modifications. The contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report. The contractor shall provide the revised final report (and documented changes to the report) to the WACOR for review. Upon the WACOR's approval, the contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the WACOR...

MEETINGS, CONFERENCES, TRAINING EVENTS, AWARD CEREMONIES AND RECEPTIONS:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA Contract Level Contracting Officer Representative (COR) as needed and provided to the contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA COR.

TECHNICAL DIRECTION:

The COR or an authorized individual is permitted to provide technical direction. Technical direction must be within the statement of work of the contract and includes: (1) Direction to the contractor which assists the contractor in accomplishing the Statement of Work, (2) Comments on and approval of reports or other deliverables. Technical direction will be issued in writing or confirmed in writing within five (5) calendar days after verbal issuance. One copy of the technical direction memorandum will be forwarded to the Contracting Officer and the Contracting Officer Representative.

CONTRACTOR IDENTIFICATION:

Contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, Contractor personnel shall wear a badge which identifies the individual as a contractor employee. Contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

SPECIAL CONDITIONS:

A. The contractor shall provide all materials written under these tasks to the EPA WACOR, as per work assignment, in electronic form and 5 hard copies of the final products. Electronic versions shall be in Microsoft Word and/or PDF.

B. The contractor shall provide signed copies of all consultant agreements for the experts required in support of this work assignment to the EPA Contracting Officer.

CONFIDENTIALITY:

Some of the work assigned under these tasks will be to draft, edit and review sensitive program and organizational information. The contractor shall not discuss the contents of the conference or meeting discussions with anyone that did not participate in those discussions.

NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT:

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the EPA COR or the EPA Contracting Officer.

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Performance Work Statement ICF Contract # EP-C-11-005 Work Assignment #5-11

Title: Support for Developing Technical Support Materials for Deriving Site-Specific Water Quality Criteria Based on Alternative Health Relationships

Work Assignment Contracting Officer Representative (WACOR):

John Ravenscroft (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
1200 Pennsylvania Ave, N.W.

Washington, DC 20460 Phone (202) 566-1101

E-mail: ravenscroft.john@epa.gov

Alternate WACOR: Shamima Akhter (Mail Code 4304T)

Health and Ecological Criteria Division

Office of Science and Technology, Office of Water

1200 Pennsylvania Avenue, NW

Washington DC, 20460 Phone: 202-566-1341

E-mail: akhter.shamima@epa.gov

Period of Performance: Work Assignment Issuance through June 30, 2016

**Note: No CBI data will be needed in the course of this work assignment.

Contractor PWS: 3.1, 3.3, 3.6

Goal: The overall goal of this work assignment is to develop implementation guidance for States and Tribes to use in developing site-specific water quality criteria based on alternative human health associations with water quality measures.

Objectives:

1. Produce a comprehensive report for internal EPA evaluation detailing the framework, process, and scientific foundation that the intended end users of this information (i.e., States, Tribes, and EPA) can utilize in developing and evaluating a site-specific water

- quality standards package based on an alternative human health relationship with water quality.
- 2. Respond to EPA and peer review comments on the report covered in Objective 1.
- 3. Produce a polished report in response to Objective 2 that the Agency can publish on its website
- 4. Produce communications materials to accompany reports including: a 1 to 2 page nontechnical synopsis, a technical summary document written in non-academic style for a non-scientific audience, a 'questions and answers' (Q&As) document covering areas of potential inquiry from nontechnical and technical audiences (both internal and external), and others as determined by the EPA WACOR via technical direction.

Background: EPA recently issued new CWA 304(a) Recreational Water Quality Criteria (RWQC) at the end of 2012. The science underpinning the new criteria describes human health effects and water quality studies conducted in waters impacted primarily by human sources of fecal contamination. EPA recommended water quality criteria for fecal indicator bacteria based on the epidemiological studies conducted by EPA's Office of Research and Development (ORD). These studies were conducted at a subset of recreational waters impacted by human fecal contamination. While EPA considers these recommended criteria to be scientifically defensible and protective of the use on a national basis, the Agency recognized that certain site-specific conditions exist that would allow alternative, equally protective, criteria to be considered for Water Quality Standards. EPA clarified additional potential approaches to developing site-specific water quality criteria in Section 6 of the RWQC published in December 2012. These approaches focused on three main areas: 1) alternative indicators; 2) alternative sources of fecal contamination; and 3) alternative health relationships. This work assignment addresses the alternative health relationship approach.

Generally speaking, the alternative health relationship approach would consist of the development of a site-specific recreational water quality criteria derived from a human health association with water quality that differs from the one EPA has used as the basis for the nationally-applicable 2012 recommendations. EPA has committed to publishing implementation guidance, hereafter termed Technical Support Materials (TSM), for use by States and Tribes who may be interested in pursuing the development of site-specific criteria. This work assignment covers the various aspects needed to develop these TSM, including the collation and development of background and supplemental information needed for the application of this approach in the development of site-specific Water Quality Standards packages to be evaluated by EPA.

Task Knowledge and Skills Required: The contractor shall have expertise in preparing the materials associated with this work assignment and be knowledgeable with the various fields of

discipline discussed, including epidemiology, microbial risk assessment, biostatistics, and environmental microbiology. The contractor shall be familiar with the different programs under the CWA, use of water quality monitoring, determination of human exposure to environmental contaminant sources, and gastrointestinal (or other) disease endpoints, applications of epidemiological data, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development. The contractor shall also be able to communicate the study outcomes and recreational outbreak data to a non-technical audience.

Quality Assurance: The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment.

Task 1: Work plan, monthly progress reports and quality assurance

Task 1.1: Work plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.2: Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The WACOR will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the checklist.

Task 2: General Project Support and Development of TSM Considering Alternative Health Relationships

EPA is planning to make available guidance to States for consideration in developing site-specific Water Quality Standards (WQS) packages utilizing alternative human health associations with water quality measures. Task 2 comprises the different facets of the guidance development project and includes project planning, communication strategies, and document preparation.

Task 2.1. Project planning and management - This task is complete.

Task 2.2. Project communication support

The contractor shall, based on technical direction given by the WACOR, provide support in preparing interim project updates and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractor may be requested to participate in briefings and meetings. The contractor may also be directed to prepare reports for communication outside the EPA based on deliverables generated by tasks under this work assignment. The contractor shall coordinate with the WACOR for the proper timing and need for these activities.

Interpretation and meta-analyses of epidemiological evidence are two potential technical areas that will need to be considered in the preparation of the TSM. The contractor shall anticipate the need to discuss specific topics of a highly technical nature with ORD epidemiologists and also to convey the outcomes of such discussions to a non-technical audience.

Task 2.3: TSM document development

The purpose of this task is to develop a guide for use by States and localities for the purposes of deriving site-specific water quality criteria derived from alternative human health relationships to water quality, including information for evaluating the technical basis for the site-specific criteria. This guide should also provide information for EPA, particularly for Regional personnel who are tasked to evaluate State WQS packages. This document shall discuss a process to help States determine if a water body is eligible for the development of site-specific criteria, what information can be used to provide a line of evidence approach for demonstrating human health relationships with water quality, the differing approaches to establishing human health relationships with water quality, a comparison of site-specific health relationships to those used by EPA as a basis for the nationally recommended water quality criteria, a potential epidemiological and Quantitative Microbial Risk Assessment (QMRA) hybrid approach for demonstrating human health relationships, how to prepare a site-specific water quality standards package, and other topics as needed to be specified by the WACOR (and in consultation with HECD's partners in SHPD). The main goal for this deliverable is to produce guidance for use by States in developing microbial WQS that are scientifically defensible, protective of the recreational designated use, and meet EPA standards for consideration and potential approval.

This contractor submitted a revised draft, including addressed peer reviewer comments, to EPA in the previous contract period. The revised draft is currently in management review prior for clearance and approval. The contractor shall revised the draft based on any final management comments provided by the WACOR.

The final deliverable shall be Section 508 compliant as specified in the US Rehabilitation Act for internet-based publications.

This task will require the contractor to attend meetings with the WACOR and other staff at EPA Headquarters during the period of performance for the purposes of project updates, planning and communication.

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the WACOR as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the CL-COR.

General Requirements of the Work Assignment and Schedule:

<u>Due Dates</u>: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

<u>Delays</u>: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

<u>Draft Documents</u>: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.

<u>Final Documents</u>: The contractor shall submit final documents both electronically and in hardcopy to the WACOR.

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Workplan	1.1	Per contract requirements
Information Quality Guidelines	1.2	Discuss with EAP WACOR within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
Task 2: General Project Support		
Project Planning and Management	2.1	Task is complete.
Project Communications Support	2.2	After the workplan approval, throughout the period of performance. Communication materials will be informed by the results and be targeted for different audiences.

		Contractor shall coordinate with EPA WACOR on the
		response to management comments. Revised document
Took missel Commont Materials	2.3	for 508 compliance and final QA – within 4 weeks after
Technical Support Materials	2.5	EPA sends the Contractor the clearance round of
		comments. There may be multiple rounds or multiple
		sets of management comment in final stage.

Technical Direction:

The COR or an authorized individual is permitted to provide technical direction. Technical direction must be within the statement of work of the contract and includes: (1) Direction to the contractor which assists the contractor in accomplishing the Statement of Work, (2) Comments on and approval of reports or other deliverables. Technical direction will be issued in writing or confirmed in writing within five (5) calendar days after verbal issuance. One copy of the technical direction memorandum will be forwarded to the Contracting Officer and the Contracting Officer Representative.

Contractor Identification:

Contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, Contractor personnel shall wear a badge which identifies the individual as a contractor employee. Contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

Confidentiality:

Some of the work assigned under these tasks will be to draft, edit and review sensitive program and organizational information. The contractor shall not discuss the contents of the conference or meeting discussions with anyone that did not participate in those discussions.

Notice Regarding Guidance Provided under this Work Assignment:

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the EPA COR or the EPA Contracting Officer.

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The purpose of this amendment is to hereby cancel Work Assignment 5-11. The contractor must seize all work													
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PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-11-005 WORK ASSIGNMENT #5-13

Title: Quantitative Microbial Risk Assessment (QMRA) to support EPA's potable water reuse efforts

Work Assignment Contract Officer Representative (WACOR):

Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740

E-mail: nappier.sharon@epa.gov

Alternate WACOR: John Ravenscroft (4304T)

Health and Ecological Criteria Division

Office of Water, Office of Science and Technology

1200 Pennsylvania Ave, N.W.

Washington, DC 20460 Phone (202) 566-1125

E-mail: ravenscroft.john@epa.gov

Period of Performance: January 1, 2016 through June 30, 2016

Contractor SOW: 3.1, 3.2, 3.3, 3.4, 3.6

**Note: No CBI data will be needed in the course of this work assignment.

Background:

Currently there are no Federal regulations for water reuse. Rather, water reclamation and reuse standards in the United States are the responsibility of state and local agencies. In 1980, EPA developed the first *Guidelines for Water Reuse* as a technical research report for ORD. There have been several updates to this Guidance, with the most recent being the *2012 Guidelines for Water Reuse*.

Indirect Potable Reuse (IPR) occurs when a utility discharges reclaimed water (treated effluent) to an environmental buffer such as a surface water or groundwater supply and this reclaimed water augments the drinking water supply.

Direct Potable Reuse (DPR), for the purposes of this PWS, means the use of water from a regulated wastewater treatment or recycling facility that is introduced into the drinking water treatment facility without the use of an environmental buffer. For the purposes of

this PWS, DPR *does not* include the introduction of water from a recycling facility *directly* into a drinking water distribution system.

Non-potable Reuse (NPR) is the use of reclaimed water for recreational, agricultural or other uses where direct human ingestion of the water does not occur. Recreational non-potable reuse can include snowmaking. Agricultural non-potable water reuse includes irrigation of food crops intended for human or animal consumption.

Water availability and drought are driving a number of states to examine water reuse as an alternative source of water for potable and non-potable applications. In many states, drinking water utilities are at various stages in considering implementing water reuse. An increasing number of states have been contacting EPA asking for guidance when they are approached by utilities that are contemplating or commencing the process of implementing DPR. As of the writing of this PWS, a number of states have adopted regulations, guidelines or design standards to cover their water reuse activities. Several states address direct or indirect potable reuse including California, Arizona, New Mexico, Texas, Colorado, Florida, Georgia, Virginia, Wyoming and Washington.

However, there are still scientific gaps relating to potable and non-potable water reuse safety, especially because states are moving forward with different standards and treatment trains and because there is a gap in the knowledgebase for assessing potential human health risks from various routes of exposure to recycled water. For example, many of these safety concerns relate to the risks associated with exposure to chemicals (including mixtures) and microbes in the finished potable water. This work assignment will address human health risks via Quantitative Microbial Risk Assessment (QMRA) from pathogen exposures to various potable and non-potable reuse applications and subsequent exposure routes, including treatment trains currently in use or currently under consideration .

Quality Assurance:

The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved contract-level QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment.

Performance Work Statement: The scope of work in this assignment will fall under the following task areas:

Task 1: Work plan and monthly progress reports

Task 1.1 Work Plan

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the WACOR via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.2 Information Quality Guidelines

The contractor shall ensure the products developed under this WA comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The WACOR will provide the checklist to the contractor. The contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this WA. The contractor shall provide the memo at the time it delivers the Final Summary Report. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the checklist.

TASK 2 – Quantitative Microbial Risk Assessment of Water Reuse Scenarios

The contractor shall develop QMRAs to support HECD efforts to estimate human health risks from various exposure routes and water reuse scenarios. The scenarios may range from indirect to direct reuse applications. The contractor shall develop appropriate planning and scoping activities prior to conducting risk analyses. Planning and scoping activities will include the delineation of the important risk management questions and potential science gaps that the assessment could address. Additionally, these activities

shall include the identification of the exposure routes of interest, relevant pathogens and pathogen indicators, etc. The contractor shall also develop a problem formulation, including a data inventory, for any reuse scenario that is modeled. The contractor shall develop a risk characterization for each QMRA conducted under this task that discusses the interpretation of the risk modeling and analyses. This interpretation shall be a synthesis exercise and include sensitivity and uncertainty analysis and interpretation. The contractor shall frame the risk characterization to reflect the problem formulation such that it is useful for informing decision-making at the EPA. The contractor shall coordinate these activities with the WACOR and other technical staff.

Task 2.1 Distributions of Pathogens and pathogen indicators

As part of ongoing work in 4-13, the contractor shall create, as specified by the WACOR, distributions of pathogenic protozoa, bacteria, and viruses in raw sewage, and in wastewater that has undergone various stages of treatment or retention time in environmental matrices. Viruses can include norovirus, adenovirus, rotavirus, etc. Protozoans can include, but are not limited to, *Giardia spp.* and *Cryptosporidium spp.* Bacteria can include, but are not limited to, *Legionella* spp., *E. coli* O157:H7, *Campylobacter* spp., etc. Additionally, the contractor may also be required to develop distributions of pathogen indicators as needed and specified by the WACOR.

Task 2.2 QMRA of Multiple Treatment Trains

Using the pathogen distribution information developed under task 2.1, the contractor shall conduct a QMRA for estimating human health risks from exposure to waters that have undergone multiple treatment trains and are intended for use under a DPR scenario. Multiple treatment trains, such as Full Advanced Treatment (FAT), will be explored. Additionally, multiple disinfectant regimes may be explored.

Task 2.3 Other QMRAs

As directed by the WACOR, the contractor shall conduct a QMRA for other exposure and water reuse scenarios as needed to help inform decision making in EPA's Office of Water.

Task 2.4 EPA Reports and Peer-review Publications

The contractor shall submit the QMRA work as both an EPA report for internal review and as a peer-review publication manuscript. EPA anticipates there will be several internal reviews of both the EPA report and manuscript prior to publication. The contractor shall assist in incorporating comments and edits and deliver final products. Manuscripts shall be prepared once the submitted report is of sufficient quality for publication. At the WACOR's direction, the contractor shall make the final EPA document 508 compliant.

Travel: Local travel is anticipated for this Task. No contractor travel outside of the Washington, D.C. metro area is required.

Task Area 3 - General Project Support

The contractor shall, based on technical direction given by the WACOR, provide support in conducting literature searches of the peer reviewed scientific literature and in preparing interim project updates and other materials for internal and external audiences. Literature searches will aid the development of the QMRAs conducted under Task 2. Updates and other support materials may include, but are not limited to, short briefing documents, white papers and PowerPoint presentations. The contractors may also be directed to participate in and/or conduct briefings. A weekly update call with the WACOR will be required for this work assignment, as needed.

Some meetings may require contractor support and/or attendance for note-taking, presentations, and/or meeting preparation materials. Details on travel dates and locations will be provided by the WACOR through technical direction, as further information becomes available.

Travel: Travel may be needed as deemed necessary by the WACOR.

Knowledge and Skills Required: The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology. The contractor shall be familiar with viral, protozoan, and bacterial indicators and pathogens, microbiological analytical methods (including molecular techniques), biostatistics, quantitative microbial risk assessment, environmental engineering, and direct and indirect potable water reuse. The contractor shall be familiar with the interpretation of indicator and pathogen monitoring results and how those results are related to risk estimates and public health protection.

General Requirements of the Work Assignment and Schedule:

<u>Due Dates</u>: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

<u>Delays</u>: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

<u>Draft Documents</u>: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. WACOR will provide comments on draft submissions prior to submission of final documents.

<u>Final Documents</u>: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Task 1: Work plan, monthly progress reports and QA Workplan 1.1 Within 15 calendar days of receipt of work assignment. Discuss with WACOR within 15 calendar days of receipt of work assignment. UG checklists due with final deliverable (can be included with QA materials). Initial planning meeting to be held within 15 calendar days of receipt of work assignment. Subsequent meetings to be held roughly weekly, as needed. For each QMRA that is conducted, the contractor shall meet with the WACOR to discuss planning and develop the problem formulation. Distributions of pathogens and pathogen indicators 2.1 Final distributions – within five months of receipt of work assignment. QMRA of Multiple Treatment Trains 2.2 Final QMRA - within five months of receipt of work assignment. Other QMRAs 2.3 TBD Unless specified by the WACOR, the schedule for report and manuscript deliverables is as follows (please note that not all draft deliverable milestones will apply to all deliverables): Draft for peer review – 2 weeks after receiving WACOR comments; Final for Mgmt review – 2 weeks after receiving peer review comments; Final for Mgmt review – 2 weeks after receiving EPA Mgmt. comments; Final for mgmt review — 2 weeks after receiving EPA Mgmt comments. Manuscripts: Draft for mgm review – 2 weeks after receiving EPA Mgmt comments; Final for publication – 2 weeks after receiving EPA Mgmt comments; Final for mgmt review – 2 weeks after receiving EPA Mgmt comments; Final for publication – 2 weeks after receiving EPA Mgmt comments; Final for publication – 2 weeks after receiving EPA Mgmt comments; Final for mgmt review – 2 weeks after receiving EPA Mgmt comments; Final for publication – 2 weeks after receiving EPA Mgmt comments; Final for publication – 2 weeks after receiving EPA Mgmt comments; Final for publication – 2 weeks after receiving EPA Mgmt comments and approval.	Task	Task #	Milestones and Due Dates
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PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-11-005 WORK ASSIGNMENT #5-13 Amendment 1

Title: Quantitative Microbial Risk Assessment (QMRA) to Support EPA's Potable Water Reuse Efforts

Work Assignment Contracting Officer Representative (WACOR):

Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740

E-mail: nappier.sharon@epa.gov

Alternate WACOR: John Ravenscroft (Mail Code 4304T)

Health and Ecological Criteria Division

Office of Water, Office of Science and Technology

1200 Pennsylvania Ave, N.W.

Washington, DC 20460 Phone (202) 566-1101

E-mail: ravenscroft.john@epa.gov

Period of Performance: Work Assignment Amendment thru August 31, 2016

Contractor SOW: 3.1, 3.2, 3.3, 3.4, 3.6

Purpose of Amendment: : The purpose of this work assignment amendment is to provide additional LOE to support efforts related to efforts related to the QMRA of direct potable reuse applications. $Tasks\ 1 - Tasks\ 3$ remain the same, no change. The contractor shall submit a revised cost estimate within 5 days after receipt of this amendment.

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Information Quality Guidelines	1.2	Discuss with EAP WAM within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).

Task 2: Quantitative Microbial Risk Assessment		
Distributions of pathogens and pathogen indicators	2.1	COMPLETED
QMRA of Multiple Treatment Trains	2.2	COMPLETED
Other QMRAs	2.3	TBD
EPA Reports and Peer-review Publications	2.4	Unless specified by the EPA WAM, the schedule for report and manuscript deliverables is as follows (please note that not all draft deliverable milestones will apply to all deliverables): Reports: Draft for mgmt review – 2 weeks after receiving EPA WAM comments; Draft for peer review – 1 week after receiving EPA Mgmt. comments; Final for Mgmt review – 2 weeks after receiving peer review comments; Final for publication – 2 weeks after receiving EPA Mgmt comments. Manuscripts: Draft for mgmt review – 2 weeks after receiving EPA WAM comments; Final – 1 week after receiving EPA Mgmt comments and approval.
Task 3: General Project Support		TBD

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Work Assignment Manager Name Sharon Nappier					Bra	Branch/Mail Code:					
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(Signature) (Date)						FAX Number:					
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PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-11-005 WORK ASSIGNMENT #5-13 Amendment 2

Title: Quantitative Microbial Risk Assessment (QMRA) to Support EPA's Potable Water Reuse Efforts

Work Assignment Contracting Officer Representative (WACOR):

Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Phone (202) 566-0740

E-mail: nappier.sharon@epa.gov

Alternate WACOR: John Ravenscroft (Mail Code 4304T)

Health and Ecological Criteria Division

Office of Water, Office of Science and Technology

1200 Pennsylvania Ave, N.W.

Washington, DC 20460 Phone (202) 566-1101

E-mail: ravenscroft.john@epa.gov

Period of Performance: Work Assignment Amendment thru September 30, 2016

Contractor SOW: 3.1, 3.2, 3.3, 3.4, 3.6

Purpose of Amendment: : The purpose of this work assignment amendment is to provide additional LOE to support efforts related to efforts related to the QMRA of direct potable reuse applications. $Tasks\ 1 - Tasks\ 3$ remain the same, no change. Travel for up to two trips have been added. Travel details will be provided by the WACOR. The contractor shall submit a revised cost estimate within 5 days after receipt of this amendment.

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Information Quality Guidelines	1.2	Discuss with WACOR within 15 calendar days of receipt of work assignment amendment. IQG checklists due with final deliverable (can be included with QA materials).

Task 2: Quantitative Microbial Risk Assessment		
Distributions of pathogens and pathogen indicators	2.1	COMPLETED
QMRA of Multiple Treatment Trains	2.2	COMPLETED
Other QMRAs	2.3	TBD
EPA Reports and Peer-review Publications	2.4	Unless specified by the WACOR, the schedule for report and manuscript deliverables is as follows (please note that not all draft deliverable milestones will apply to all deliverables): Reports: Draft for Mgmt review – 2 weeks after receiving WACOR comments; Draft for peer review – 1 week after receiving EPA Mgmt. comments; Final for Mgmt review – 2 weeks after receiving peer review comments; Final for publication – 2 weeks after receiving EPA Mgmt comments. Manuscripts: Draft for Mgmt review – 2 weeks after receiving WACOR comments; Final – 1 week after receiving EPA Mgmt comments and approval.
Task 3: General Project Support		TBD

	United States Environmental Protection Agency			Work Assignment Number				
EPA		Washington, DC 20460 Work Assignment				5-14		
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PERFORMANCE WORK STATEMENT ICF CONTRACT EP-C-11-005 WORK ASSIGNMENT #5-14

Title: Activities to support the development of human health AWQC for Cyanotoxins

Work Assignment Contracting Officer Representative (WACOR):

John Ravenscroft (Mail Code 4304T) Health and Ecological Criteria Division

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Alternate WACOR: Lesley D'Anglada (Mail Code 4304T)

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E-mail: danglada.lesley@epa.gov

Period of Performance: January 1, 2016 through June 30, 2016

Contractor SOW: 3.1, 3.4, 3.5, 3.6

**Note: No CBI data will be needed in the course of this work assignment.

Background:

National Ambient Water Quality Criteria (AWQC) are established by the United States Environmental Protection Agency (EPA) pursuant Section 304(a) of the Clean Water Act (CWA). The main goal of the CWA is to restore and maintain the chemical, physical, and biological integrity of the nation's waters. AWQC are recommendations developed and published by the EPA reflecting the latest scientific knowledge: (A) on the kind and extent of all identifiable effects on health and welfare including, but not limited to, plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics, and recreation which may be expected from the presence of pollutants in any body of water, including ground water; (B) on the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes; and (C) on the effects of pollutants on biological community diversity, productivity, and stability, including information on the factors affecting rates of eutrophication and rates of organic and inorganic sedimentation for varying types of receiving waters. CWA §304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water. They are a non-regulatory, scientific

assessment of effects on human health or aquatic life. The criteria recommendations developed from this effort are intended to be such scientific assessments.

EPA's AWQC recommendations may be used by the states to establish water quality standards (WQS), and if adopted in state WQS and approved by EPA, will ultimately provide a basis for protecting the health of those recreating on or in the nation's waters. Additionally, the criteria also provide guidance to EPA when promulgating WQS for states under CWA §303(c), when such actions are necessary. When states adopt new or revised AWQC into WQS, they must be scientifically defensible and protective of the designated uses of the waterbodies. EPA's regulation 40 CFR §131.11(b)(1) provides that "In establishing criteria, states should (1) Establish numerical values based on (i) 304(a) Guidance; or (ii) 304(a) Guidance modified to reflect site-specific conditions; or (iii) Other scientifically defensible methods." For example, EPA published human health recreational water quality criteria (RWQC) recommendations in 2012 to describe the desired ambient water quality conditions to support the designated use of primary contact recreation (EPA, 2012). The 2012 RWQC are designed to protect swimmers from excess gastrointestinal illness caused by pathogens present in fecal contamination of waterbodies. This §304(a) criteria document recommends ambient water quality criteria values for cyanotoxins that would be protective of human health given a primary contact recreational exposure scenario. The cyanotoxins included in this effort have been demonstrated to occur in nutrient-enriched waters affected by harmful algal blooms (HABs). Any recommended values produced from this effort do not replace or supersede the 2012 RWQC recommendations for recreational waters. Rather they are offered to supplement the 2012 RWQC to provide additional public health protection for additional, potentially hazardous conditions found in ambient recreational waters.

The water quality criteria developed from this effort are national ambient water quality criteria recommendations for the protection of human health. Unless expressly indicated otherwise, all references to "criteria", "water quality criteria", "ambient water quality criteria (AWQC) recommendations," or similar variants thereof, are references to national ambient water quality criteria recommendations for human health.

Quality Assurance:

The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP (date: March 2012). Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the WACOR before activities covered by the additional QA language begin under this work assignment.

Performance Work Statement (PWS): The scope of work in this assignment will fall under the following task areas:

Task Area 1 - Workplan and Monthly Progress Reports

Task Area 1.1. Work Plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task Area 1.2. Monthly Progress Reports

This task includes monthly progress and financial reports. The monthly progress report shall indicate in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.3: Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The WACOR will provide the checklist to the contractor. The contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the checklist.

Task Area 2 - Support for developing and editing cyanotoxin AWQC and AWQC-related documents

Task Area 2.1. AWQC development

The contractor shall assist the WACOR in developing AWQC documents or other related documents for cyanotoxins for the protection of human health. Risks from microbes can arise from either infections due to pathogenic organisms or by intoxications via substances produced by microbes. Cyanotoxins fall into the second category. Cyanotoxins are produced by cyanobacteria, also known as 'blue-green algae,' and are classified as microbial pollutants. The contractor shall refer to EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (2000) for a discussion of EPA's approved framework and parameter selection process. The contractor shall also refer to the problem formulation supplied

by the WACOR to help guide this process. The document shall conform to Agency risk assessment guidance and be accessible to a non-technical audience for the purposes of informing decision-making. This task is iterative in nature and may require multiple revisions prior to developing draft AWQC documents. Analyses of monitoring data, such as characterizing correlations between toxin levels in surface waters and cyanobacterial cell counts or total phosphorus concentrations, may be necessary to support decisions in the development of the AWQC.

The contractor submitted a draft problem formulation in 2015. This deliverable is still in review by EPA. When comments are received, the contractor shall work with the WACOR to address them.

The contractor shall perform technical and editorial edits for all documents prepared and submit to the WACOR. Items, such as active voice and clear writing style, shall be addressed prior to submitting milestone deliverables (e.g., draft) to EPA. The contractor shall meet with the WACOR to discuss project planning and scoping prior to beginning work and then periodically thereafter, as needed.

Task Area 2.2. Prepare briefing materials and other supporting documents to aid in AWQC development and communication efforts

Briefing materials and other supporting documents will be needed during Option Selection, Final Agency Review, and during other parts of the Criteria development process. The contractor shall aid the in the development of any materials or presentations for these purposes. It is anticipated that major decision points and/or document development milestones will require management briefings and supporting materials.

Task Area 3 – Response to Comments

Task Area 3.1. Organizing and responding to comments.

Draft AWQC will undergo several types of reviews before a final version is posted, including: internal management and technical reviews, expert peer-reviews, and public comment period. The contractor shall assist the WACOR with the response to comments for all reviews, revise the AWQC documents as directed, and provide an updated version to the WACOR. For the draft document, the contractor can anticipate internal and external technical peer review comments—approximately 3 to 5 sets of comments for each—and internal EPA office review comments. Additionally, the contractor should anticipate 3 rounds of management review at various levels.

Task Area 3.2. Public Comment Analysis for the AWQC.

Public comments on the AWQC could be significant. Should this be the case, the contractor shall discuss with the WACOR potential options for managing the comment response, including electronic tracking and sorting. Because it is early in the AWQC development process and the number of potential comments is unknown, the contractor can provide a "best guess" estimate in the workplan. As a comparison, the 2012 Recreational Water Quality Criteria document received approximately 1000 comments during the public comment period. However, EPA cannot anticipate the breadth or the depth of public comments on this AWQC.

Task Area 4 – Gathering and preparing materials for the EPA docket

A "docket" is a collection of documents made available by an agency for public viewing often associated with an opportunity for public comment. EPA's dockets consist of materials used in developing a particular rulemaking or other action issued by the Agency.

Task Area 4.1. Prepare comprehensive list of materials needed in the docket

The contractor shall help identify materials that need to be placed in the EPA docket. Docket materials may include, but are not limited to, publications, data, and meeting notes.

Task Area 4.2. Gather and prepare materials needed in the docket

Once the docket materials list has been reviewed by the WACOR, the contractor shall help gather and prepare all the materials that need to be placed in the EPA docket. Again, docket materials may include, but are not limited to, publications, data, and meeting notes.

Task Area 5 – Support ongoing Action Development Process Workgroup (ADP WG) efforts in the development of the RWQC

This task will require the contractor to assist in the ongoing efforts of the ADP WG. The contractor shall attend weekly on-site ADP WG meetings, provide note-taking support, and submit meeting notes to the WACOR within 2 business days of each ADP WG meeting. Additionally, the contractor shall prepare meeting materials that may include, but are not limited to, presentations, briefing materials, hand-outs, and overviews. The number of weekly workgroup meetings will depend on the number of decisions that require inter-office input, which is not known at this time. The types of materials needed for each meeting will vary depending on the workgroup's need and topics discussed. The workgroup is likely to convene in late January or early February.

Travel: Local travel is anticipated for this Task. No contractor travel outside of the Washington, D.C. metro area is required.

Task Area 6 - General Project Support

The contractor shall, based on technical direction given by the WACOR, provide support in conducting literature searches of the peer reviewed scientific literature—to address identified data gaps the searches would be specific and targeted in nature—and in preparing interim project updates and other materials for internal and external audiences. Literature searches will aid the development of the document conducted under Task 2. It is not known at this time how many searches would be needed, but for planning purposes, the contractor may plan on four targeted searches. The contractor conducted some targeted searches in 2015 and similar levels of effort will likely be required on additional topics; for example, to support characterizing risk of the toxins to human health or to help support workgroup activities. Additionally, specific data analyses may be required for briefings and/or communication materials. Such analyses would be based on technical direction given by the WACOR. Updates and other support materials may

include, but are not limited to, short briefing documents, white papers and PowerPoint presentations. The WACOR may request the contractor to participate in and/or conduct briefings. A weekly update call with the WACOR will be required for this work assignment, as needed.

Some meetings may require contractor support and/or attendance for note-taking, presentations, and meeting preparation materials. Details on meeting dates and locations will be provided by the WACOR through technical direction, as further information becomes available. For planning purposes, the contractor can anticipate 3 meetings.

<u>Travel:</u> The contractor travel outside of the Washington, D.C. metro area may need to occur for this work assignment and shall occur only if specified by technical direction.

Knowledge and Skills Required: The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall have practical experience in conducting human health risk assessments and have advanced credentials in environmental microbiology and toxicology. The contractor shall be familiar with the use of ambient water quality monitoring to inform decision-making, microbial and chemical analytical methods (including GC/MS and ELISA), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and human health disease endpoints (e.g., gastrointestinal).

General Requirements of the Work Assignment and Schedule:

<u>Due Dates</u>: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

<u>Delays</u>: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

<u>Draft Documents</u>: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. WACOR will provide comments on draft submissions prior to submission of final documents.

<u>Final Documents</u>: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Workplan	1.1	Per contract requirements
Information Quality Guidelines	1.2	Discuss with WACOR within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).

Task 2: Support for developing and editing cyanotoxin AWQC and AWQC-related documents				
AWQC development	2.1	After the workplan approval, throughout the period of performance. Initial planning meeting to be held within 15 calendar days of receipt of work assignment. Subsequent meetings to be held roughly weekly, as needed.		
Prepare briefing materials and other supporting documents to aid in AWQC development and communication efforts	2.2	TBD		
Task 3: Response to Comments				
Organizing and responding to comments	3.1	Will occur periodically throughout the period of performance during management and technical reviews of draft and final, as well as, in response to external peer review. Exact dates TBD.		
Public Comment Analysis for the AWQC	3.2	TBD		
Task 4: Gathering and preparing materials for the EPA docket				
Prepare comprehensive list of materials needed in the docket	4.1	TBD		
Gather and prepare materials needed in the docket	4.2	TBD		
Task 5: Support for ADP WG		The workgroup is likely to convene starting in late January or early February.		
Task 6: General Project Support		TBD		

MEETINGS, CONFERENCES, TRAINING EVENTS, AWARD CEREMONIES AND RECEPTIONS:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA Contract Level Contracting Officer Representative (COR) as needed and provided to the contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the WACOR.

TECHNICAL DIRECTION:

The WACOR or an authorized individual is permitted to provide technical direction. Technical direction must be within the statement of work of the contract and includes: (1) Direction to the contractor which assists the contractor in accomplishing the Statement of Work, (2) Comments on and approval of reports or other deliverables. Technical direction will be issued in writing or confirmed in writing within five (5) calendar days after verbal issuance. One copy of the technical direction memorandum will be forwarded to the Contracting Officer and the Contracting Officer Representative.

CONTRACTOR IDENTIFICATION:

The contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, contractor personnel shall wear a badge which identifies the individual as a contractor employee. The contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

SPECIAL CONDITIONS:

A. The contractor shall provide all materials written under these tasks to the WACOR, as per work assignment, in electronic form and 5 hard copies of the final products. Electronic versions shall be in Microsoft Word and/or PDF.

B. The contractor shall provide signed copies of all consultant agreements for the experts required in support of this work assignment to the EPA Contracting Officer.

CONFIDENTIALITY:

Some of the work assigned under these tasks will be to draft, edit and review sensitive program and organizational information. The contractor shall not discuss the contents of the conference or meeting discussions with anyone that did not participate in those discussions.

NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT:

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the WACOR or the EPA Contracting Officer.

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Performance Work Statement ICF Contract # EP-C-11-005 Work Assignment #5-14 Amendment 1

Title: Activities to support the development of human health AWQC for Cyanotoxins

Work Assignment Contracting: John Ravenscroft (Mail Code 4304T)

Officer Representative (WACOR) Office of Water, Office of Science and Technology

Health and Ecological Criteria Division

1200 Pennsylvania Ave, N.W.

Washington, DC 20460 Phone (202) 566-1101

E-mail: ravenscroft.john@epa.gov

Alternate WACOR: Lesley D'Anglada (Mail Code 4304T)

Health and Ecological Criteria Division

Office of Water, Office of Science and Technology

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460 Phone (202) 566-1125

E-mail: danglada.lesley@epa.gov

Contractor PWS: 3.1, 3.4, 3.5, and 3.6

Period of Performance: WA Amendment Issuance through June 30, 2016

**Note: No CBI data will be needed in the course of this work assignment.

Purpose of Amendment: The purpose of this amendment is to add additional LOE for Tasks 2 and 5. The process for developing the AWQC document has entailed substantially more comment response, additional rounds of review and editing, preparation of background materials, especially for management briefings and internal and external meetings, than what was originally planned under the existing workplan. As a result, the original workplan estimate will be insufficient to cover the entire period of performance. The month of June will be a crucial time in the AWQC development process and EPA's goal is to have a solid draft AWQC document that would be sufficient to submit for external peer review. The additional LOE will help to prepare the draft AWQC deliverable of sufficient quality for EPA and maintain project timelines.

The language contained in the original work assignment still applies (e.g., Information Quality Guidelines, QA section, etc.). The contractor shall submit a revised cost estimate within 5 days after receipt of this amendment.

EPA	United States Environm Washing	ental Protection A	Agency		Work Assignment Nu	umber	
EPA	Work As	ssignment			Other	X Amendm	ent Number: 1
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Performance Work Statement ICF Contract # EP-C-11-005 Work Assignment #5-14 Amendment 2

Title: Activities to support the development of human health AWQC for Cyanotoxins

Work Assignment Contracting: John Ravenscroft (Mail Code 4304T)

Officer Representative (WACOR) Office of Water, Office of Science and Technology

Health and Ecological Criteria Division

1200 Pennsylvania Ave, N.W.

Washington, DC 20460 Phone (202) 566-1101

E-mail: ravenscroft.john@epa.gov

Alternate WACOR: Lesley D'Anglada (Mail Code 4304T)

Health and Ecological Criteria Division

Office of Water, Office of Science and Technology

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460 Phone (202) 566-1125

E-mail: danglada.lesley@epa.gov

Contractor PWS: 3.1, 3.4, 3.5, and 3.6

Period of Performance: WA Amendment Issuance through August 31, 2016

**Note: No CBI data will be needed in the course of this work assignment.

Purpose of Amendment: The purpose of this amendment is to provide additional LOE for the development of human health AWQC for Cyanotoxins. A first draft of the document was submitted by the Contractor in June 2016 and is currently undergoing review by HECD management. For the extension of the period of performance, the Contractor shall continue to assist EPA with comment response, document revisions and preparation of background materials. The additional LOE will help to prepare the draft AWQC deliverable of sufficient quality for EPA and maintain project timelines.

The language contained in the original work assignment still applies (e.g., Information Quality Guidelines, QA section, etc.). The contractor shall submit a revised cost estimate within 5 days after receipt of amendment.

Quality Assurance: The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP (date: March 2012). Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the WACOR before activities covered by the additional QA language begin under this work assignment.

General Requirements of the Work Assignment and Schedule:

Due Dates: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. WACOR will provide comments on draft submissions prior to submission of final documents.

Final Documents: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Milestone/Deliverable Table.

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Information Quality Guidelines	1.2	Discuss with WACOR within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).

Task 2: Support for developing and editing cyanotoxin AWQC and AWQC-related documents		
AWQC development	2.1	After the workplan approval, throughout the period of performance. Subsequent meeting to be held roughly weekly, as needed.
Prepare briefing materials and other supporting documents to aid in AWQC development and communication efforts	2.2	TBD
Task 3: Response to Comments		
Organizing and responding to comments	3.1	Will occur periodically throughout the period of performance during management and technical review of draft and final, as well as, in response to external peer review. Exact dates TBD.
Public Comment Analysis for the AWQC	3.2	TBD
Task 4: Gathering and preparing materials for the EPA docket		
Prepare comprehensive list of materials needed in the docket	4.1	Ongoing throughout the period of performance.
Gather and prepare materials needed in the docket	4.2	Ongoing throughout the period of performance.
Task 5: Support for ADP WG		Ongoing throughout the period o performance.
Task 6: General Project Support		TBD

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Performance Work Statement ICF Contract # EP-C-11-005 Work Assignment #5-14 Amendment 3

Title: Activities to support the development of human health AWQC for Cyanotoxins

Work Assignment Contracting: John Ravenscroft (Mail Code 4304T)

Officer Representative (WACOR) Office of Water, Office of Science and Technology

Health and Ecological Criteria Division

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Contractor PWS: 3.1, 3.4, 3.5, and 3.6

Period of Performance: WA Amendment Issuance through September 30, 2016

**Note: No CBI data will be needed in the course of this work assignment.

Purpose of Amendment: The purpose of this amendment is to add additional resources for the development of human health AWQC for Cyanotoxins. A draft document was submitted by the Contractor in August 2016 and is currently undergoing review by an internal EPA workgroup. For the extension of the period of performance, the Contractor shall continue to assist EPA with comment response, document revisions and preparation of background materials. The additional LOE and funding supplied by this amendment will help to prepare the draft AWQC deliverable of sufficient quality for EPA and maintain project timelines.

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Milestone/Deliverable Table.

Task	Task #	Milestones and Due Dates
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Gather and prepare materials needed in the docket	4.2	Ongoing throughout the period of performance.
Task 5: Support for ADP WG		Ongoing throughout the period of performance.
Task 6: General Project Support		TBD